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The primary study hypotheses are MK-0616 is superior to ezetimibe, bempedoic acid, and ezetimibe + bempedoic acid on mean percent change from baseline in LDL-C at week 8.'}, 'conditionsModule': {'conditions': ['Hypercholesterolemia']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE3'], 'designInfo': {'allocation': 'RANDOMIZED', 'interventionModel': 'PARALLEL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'TRIPLE', 'whoMasked': ['PARTICIPANT', 'INVESTIGATOR', 'OUTCOMES\_ASSESSOR']}}, 'enrollmentInfo': {'count': 300, 'type': 'ESTIMATED'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'MK-0616', 'type': 'EXPERIMENTAL', 'description': 'Participants receive MK-0616 20mg, ezetimibe-matching placebo, and bempedoic acid-matching placebo once daily (QD) orally up to approximately 56 days.', 'interventionNames': ['Drug: MK-0616', 'Other: Placebo for Ezetimibe', 'Other: Placebo for Bempedoic Acid']}, {'label': 'Ezetimibe', 'type': 'ACTIVE\_COMPARATOR', 'description': 'Participants receive ezetimibe 10mg, MK-0616-matching placebo, and bempedoic acid-matching placebo QD orally up to approximately 56 days.', 'interventionNames': ['Drug: Ezetimibe', 'Other: Placebo for MK-0616', 'Other: Placebo for Bempedoic Acid']}, {'label': 'Bempedoic Acid', 'type': 'ACTIVE\_COMPARATOR', 'description': 'Participants receive bempedoic acid 180mg, ezetimibe-matching placebo, and MK-0616-matching placebo QD orally up to approximately 56 days.', 'interventionNames': ['Drug: Bempedoic Acid', 'Other: Placebo for MK-0616', 'Other: Placebo for Ezetimibe']}, {'label': 'Ezetimibe + Bempedoic Acid', 'type': 'ACTIVE\_COMPARATOR', 'description': 'Participants receive ezetimibe 10 mg, bempedoic acid 180mg, MK-0616-matching placebo orally QD for approximately 56 days.', 'interventionNames': ['Drug: Ezetimibe', 'Drug: Bempedoic Acid', 'Other: Placebo for MK-0616']}], 'interventions': [{'type': 'DRUG', 'name': 'MK-0616', 'description': 'Administered orally.', 'armGroupLabels': ['MK-0616']}, {'type': 'DRUG', 'name': 'Ezetimibe', 'description': 'Administered orally.', 'armGroupLabels': ['Ezetimibe', 'Ezetimibe + Bempedoic Acid']}, {'type': 'DRUG', 'name': 'Bempedoic Acid', 'description': 'Administered orally.', 'armGroupLabels': ['Bempedoic Acid', 'Ezetimibe + Bempedoic Acid']}, {'type': 'OTHER', 'name': 'Placebo for MK-0616', 'description': 'Administered orally.', 'armGroupLabels': ['Bempedoic Acid', 'Ezetimibe', 'Ezetimibe + Bempedoic Acid']}, {'type': 'OTHER', 'name': 'Placebo for Ezetimibe', 'description': 'Administered orally.', 'armGroupLabels': ['Bempedoic Acid', 'MK-0616']}, {'type': 'OTHER', 'name': 'Placebo for Bempedoic Acid', 'description': 'Administered orally.', 'armGroupLabels': ['Ezetimibe', 'MK-0616']}]}, 'outcomesModule': {'primaryOutcomes': [{'measure': 'Mean Percent Change from Baseline in LDL-C at Day 56', 'description': 'Blood samples will be collected at baseline and after 56 days of treatment to assess mean percentage change in LDL-C. 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study\n\* Is an individual of any sex/gender, from 18 years of age inclusive, at the time of providing the informed consent\n\nExclusion Criteria:\n\n\* Has a history of homozygous familial hypercholesterolemia (FH) based on genetic or clinical criteria, compound heterozygous familial hypercholesterolemia (HeFH), or double HeFH\n\* Has New York Heart Association class IV heart failure, or last known left ventricular ejection fraction ≤25% by any imaging method, or had a heart failure hospitalization within 3 months before Visit 1 (Screening)\n\* Participants with a history of tendon disorder or tendon rupture\n\* Participants with a history of gout\n\* Is undergoing or previously underwent an LDL-C apheresis program within 3 months before Visit 1 (Screening) or plans to initiate an LDL-C apheresis program\n\* Was previously treated/is being treated with certain other cholesterol lowering medications, including ezetimibe, bempedoic acid, or protein convertase subtilisin/kexin type 9 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Participants with RI that have stable, chronic medical or psychiatric conditions, including but not limited to hypertension, hypercholesterolemia, diabetes mellitus, hyper- or hypothyroidism, gout, and chronic anxiety or depression may be included at the discretion of the investigator.\n\* Body Mass Index (BMI) ≥ 18 kg/m2 and ≤ 40 kg/m2, inclusive\n\* Be on a stable dose of any statin therapy defined as: no changes to dose or type of statin therapy for at least 2 months prior to Screening and participant anticipates no changes to statin therapy throughout the study until the poststudy visit\n\nExclusion Criteria:\n\n\* History or presence of renal artery stenosis.\n\* Had a functioning renal transplant in the past 5 years and is taking transplant medication.\n\* Participants in panels A, B and D: Has rapidly fluctuating renal function as determined by historical measurements\n\* Has a history gastrointestinal disease which might affect food and drug absorption, as determined by the investigator, or has had gastric bypass or similar surgery\n\* History of cancer (malignancy)\n\* History of significant multiple and/or severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or nonprescription drugs or food\n\* Has received an anti-proprotein convertase subtilisin/kexin type 9 (PCSK9) small molecule treatment, monoclonal antibody, or short interfering RNA (siRNA) or RNA interference (ie, Inclisiran) within 12 months prior to Screening\n\* Participants with RI (Panels A, B, and C): Taking medications to treat chronic medical conditions and/or conditions associated with renal disease, if participant has not been on a stable regimen for at least 1 month (other than statins, which require a stable dose for at least 2 months) prior to administration of the initial dose of study intervention, and/or is unable to withhold the use of the medication(s) within 4 hours prior to and 4 hours after administration of study intervention\n\* Participated in another investigational study within 4 weeks prior to the prestudy (screening) visit\n\* Consumes greater than 3 servings of alcoholic beverages per day\n\* Consumes excessive amounts, defined as greater than 6 servings of caffeinated beverages per day', 'healthyVolunteers': True, 'sex': 'ALL', 'minimumAge': '18 Years', 'maximumAge': '85 Years', 'stdAges': ['ADULT', 'OLDER\_ADULT']}, 'contactsLocationsModule': {'overallOfficials': [{'name': 'Medical Director', 'affiliation': 'Merck Sharp & Dohme LLC', 'role': 'STUDY\_DIRECTOR'}], 'locations': [{'facility': 'Velocity Clinical Research, Hallandale Beach ( Site 0003)', 'city': 'Hallandale Beach', 'state': 'Florida', 'zip': '33009', 'country': 'United States', 'geoPoint': {'lat': 25.9812, 'lon': -80.14838}}, {'facility': 'Clinical Pharmacology of Miami ( Site 0005)', 'city': 'Miami', 'state': 'Florida', 'zip': '33014-3616', 'country': 'United States', 'geoPoint': {'lat': 25.77427, 'lon': -80.19366}}, 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The primary hypothesis is that at least one of the four doses of MK-0616 tested in this study is superior to placebo on percent change from baseline in LDL-C at Week 8.'}, 'conditionsModule': {'conditions': ['Hypercholesterolemia', 'Familial Hypercholesterolemia']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE2'], 'designInfo': {'allocation': 'RANDOMIZED', 'interventionModel': 'PARALLEL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'DOUBLE', 'whoMasked': ['PARTICIPANT', 'INVESTIGATOR']}}, 'enrollmentInfo': {'count': 381, 'type': 'ACTUAL'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'MK-0616 6 mg', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 6 mg of MK-0616 orally QD for 8 weeks', 'interventionNames': ['Drug: MK-0616']}, {'label': 'MK-0616 12 mg', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 12 mg of MK-0616 orally QD for 8 weeks', 'interventionNames': ['Drug: MK-0616']}, {'label': 'MK-0616 18 mg', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 18 mg of MK-0616 orally QD for 8 weeks', 'interventionNames': ['Drug: MK-0616']}, {'label': 'MK-0616 30 mg', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 30 mg of MK-0616 orally QD for 8 weeks', 'interventionNames': ['Drug: MK-0616']}, {'label': 'Placebo', 'type': 'PLACEBO\_COMPARATOR', 'description': 'Participants will receive MK-0616-matching placebo orally QD for 8 weeks', 'interventionNames': ['Drug: Placebo']}], 'interventions': [{'type': 'DRUG', 'name': 'MK-0616', 'description': 'MK-0616 administered orally', 'armGroupLabels': ['MK-0616 12 mg', 'MK-0616 18 mg', 'MK-0616 30 mg', 'MK-0616 6 mg']}, {'type': 'DRUG', 'name': 'Placebo', 'description': 'Placebo matching MK-0616 administered orally', 'armGroupLabels': ['Placebo']}]}, 'outcomesModule': {'primaryOutcomes': [{'measure': 'Percent Change From Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 8', 'description': 'Blood samples were collected at baseline and after 8 weeks of treatment to assess mean percent change in LDL-C. 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The percentage of participants with LDL-C value at goal at week 8 were reported.', 'timeFrame': 'Week 8'}]}, 'eligibilityModule': {'eligibilityCriteria': 'Inclusion Criteria:\n\n\* History of clinical atherosclerotic cardiovascular disease (ASCVD), or has an ASCVD risk equivalent and/or a 10-year risk of having an ASCVD event ≥5.0%, AND has a corresponding LDL-C that falls within the protocol-specified range at screening.\n\* Treatment with a stable dose of one or more lipid-lowering therapies for ≥30 days before screening, or has not received treatment with any lipid-lowering therapy for ≥30 days before screening.\n\* A female participant is not pregnant or breastfeeding, not a woman of child-bearing potential (WOCBP) or is a WOCBP and agrees to follow contraceptive guidance during the intervention period and for at least 8 weeks after the last dose of study intervention.\n\nExclusion Criteria:\n\n\* History of homozygous familial hypercholesterolemia (FH) based on genetic or clinical criteria.\n\* History of nephrotic syndrome.\n\* History of unstable angina, a myocardial infarction, percutaneous transluminal coronary angioplasty, transient ischemic attack, or stroke within 3 months before Screening.\n\* Has poorly controlled diabetes mellitus, defined as hemoglobin A1C (A1C) ≥9.0% at Screening.\n\* History of malignancy ≤3 years before screening, except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer, which have no timeframe limitations relative to screening.\n\* Currently participating in or has previously participated in an interventional clinical study within 3 months before Screening.\n\* Has moderate or greater renal insufficiency.', 'healthyVolunteers': False, 'sex': 'ALL', 'minimumAge': '18 Years', 'maximumAge': '80 Years', 'stdAges': ['ADULT', 'OLDER\_ADULT']}, 'contactsLocationsModule': {'overallOfficials': [{'name': 'Medical Director', 'affiliation': 'Merck Sharp & Dohme LLC', 'role': 'STUDY\_DIRECTOR'}], 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Phase 2b Randomized Trial of the Oral PCSK9 Inhibitor MK-0616. J Am Coll Cardiol. 2023 Apr 25;81(16):1553-1564. doi: 10.1016/j.jacc.2023.02.018. Epub 2023 Mar 6.'}], 'seeAlsoLinks': [{'label': 'Merck Clinical Trials Information', 'url': 'http://www.merckclinicaltrials.com'}]}, 'ipdSharingStatementModule': {'ipdSharing': 'YES', 'description': 'http://engagezone.msd.com/doc/ProcedureAccessClinicalTrialData.pdf', 'url': 'http://engagezone.msd.com/ds\_documentation.php'}}, 'resultsSection': {'participantFlowModule': {'recruitmentDetails': 'Of 668 participants screened for inclusion, 381 were randomized 1:1:1:1:1 to receive MK-0616 6 mg, 12 mg, 18 mg, 30 mg, or placebo. 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Participants were stratified by the following renal function at baseline: eGFR ≥60 vs \\<60 ml/min/1.73 m\\^2.', 'paramType': 'COUNT\_OF\_PARTICIPANTS', 'unitOfMeasure': 'Participants', 'classes': [{'categories': [{'title': 'eGFR ≥60 ml/min/1.73 m^2', 'measurements': [{'groupId': 'BG000', 'value': '71'}, {'groupId': 'BG001', 'value': '72'}, {'groupId': 'BG002', 'value': '72'}, {'groupId': 'BG003', 'value': '71'}, {'groupId': 'BG004', 'value': '71'}, {'groupId': 'BG005', 'value': '357'}]}, {'title': 'eGFR <60 ml/min/1.73 m^2', 'measurements': [{'groupId': 'BG000', 'value': '6'}, {'groupId': 'BG001', 'value': '4'}, {'groupId': 'BG002', 'value': '4'}, {'groupId': 'BG003', 'value': '5'}, {'groupId': 'BG004', 'value': '5'}, {'groupId': 'BG005', 'value': '24'}]}]}]}, {'title': 'Baseline Low-density Lipoprotein Cholesterol (LDL-C)', 'description': 'Blood samples were taken at baseline to determine baseline LDL-C levels.', 'paramType': 'MEAN', 'dispersionType': 'STANDARD\_DEVIATION', 'unitOfMeasure': 'mg/dL', 'classes': [{'categories': [{'measurements': [{'groupId': 'BG000', 'value': '116.5', 'spread': '37.0'}, {'groupId': 'BG001', 'value': '117.3', 'spread': '36.4'}, {'groupId': 'BG002', 'value': '123.7', 'spread': '35.1'}, {'groupId': 'BG003', 'value': '119.4', 'spread': '36.7'}, {'groupId': 'BG004', 'value': '120.7', 'spread': '28.3'}, {'groupId': 'BG005', 'value': '119.5', 'spread': '34.8'}]}]}]}]}, 'outcomeMeasuresModule': {'outcomeMeasures': [{'type': 'PRIMARY', 'title': 'Percent Change From Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 8', 'description': 'Blood samples were collected at baseline and after 8 weeks of treatment to assess mean percent change in LDL-C. Based on a constrained longitudinal analysis (cLDA) model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time. The percent change from baseline in LDL-C at week 8 was reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention, had at least one observation for the analysis endpoint, and had baseline data were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'LEAST\_SQUARES\_MEAN', 'dispersionType': '95% Confidence Interval', 'unitOfMeasure': 'Percentage Change', 'timeFrame': 'Baseline and up to Week 8', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '75'}, {'groupId': 'OG001', 'value': '75'}, {'groupId': 'OG002', 'value': '74'}, {'groupId': 'OG003', 'value': '73'}, {'groupId': 'OG004', 'value': '72'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '-40.0', 'lowerLimit': '-45.2', 'upperLimit': '-34.8'}, {'groupId': 'OG001', 'value': '-54.5', 'lowerLimit': '-59.8', 'upperLimit': '-49.2'}, {'groupId': 'OG002', 'value': '-57.9', 'lowerLimit': '-63.2', 'upperLimit': '-52.6'}, {'groupId': 'OG003', 'value': '-59.7', 'lowerLimit': '-65.0', 'upperLimit': '-54.5'}, {'groupId': 'OG004', 'value': '1.2', 'lowerLimit': '-4.1', 'upperLimit': '6.5'}]}]}], 'analyses': [{'groupIds': ['OG000', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-41.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-47.8', 'ciUpperLimit': '-34.7', 'estimateComment': 'MK-0616 6 mg minus Placebo'}, {'groupIds': ['OG001', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-55.7', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-62.3', 'ciUpperLimit': '-49.1', 'estimateComment': 'MK-0616 12 mg minus Placebo'}, {'groupIds': ['OG002', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-59.1', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-65.7', 'ciUpperLimit': '-52.5', 'estimateComment': 'MK-0616 18 mg minus Placebo'}, {'groupIds': ['OG003', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-60.9', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-67.6', 'ciUpperLimit': '-54.3', 'estimateComment': 'MK-0616 30 mg minus Placebo'}]}, {'type': 'PRIMARY', 'title': 'Percentage of Participants Who Experienced One or More Adverse Events (AEs)', 'description': 'An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The percentage of participants who experienced at least one AE was reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'NUMBER', 'unitOfMeasure': 'Percentage of Participants', 'timeFrame': 'Up to approximately 17 Weeks', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '77'}, {'groupId': 'OG001', 'value': '76'}, {'groupId': 'OG002', 'value': '76'}, {'groupId': 'OG003', 'value': '76'}, {'groupId': 'OG004', 'value': '75'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '44.2'}, {'groupId': 'OG001', 'value': '39.5'}, {'groupId': 'OG002', 'value': '43.4'}, {'groupId': 'OG003', 'value': '42.1'}, {'groupId': 'OG004', 'value': '44.0'}]}]}], 'analyses': [{'groupIds': ['OG000', 'OG004'], 'nonInferiorityType': 'OTHER', 'nonInferiorityComment': 'Difference in percentage based on Miettinen \\& Nurminen method.', 'paramType': 'Difference in Percentage', 'paramValue': '0.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-15.5', 'ciUpperLimit': '15.8', 'estimateComment': 'MK-0616 6 mg minus Placebo'}, {'groupIds': ['OG001', 'OG004'], 'nonInferiorityType': 'OTHER', 'nonInferiorityComment': 'Difference in percentage based on Miettinen \\& Nurminen method.', 'paramType': 'Difference in Percentage', 'paramValue': '-4.5', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-20.0', 'ciUpperLimit': '11.2', 'estimateComment': 'MK-0616 12 mg vs Placebo'}, {'groupIds': ['OG002', 'OG004'], 'nonInferiorityType': 'OTHER', 'nonInferiorityComment': 'Difference in percentage based on Miettinen \\& Nurminen method.', 'paramType': 'Difference in Percentage', 'paramValue': '-0.6', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-16.3', 'ciUpperLimit': '15.1', 'estimateComment': 'MK-0616 18 mg vs Placebo'}, {'groupIds': ['OG003', 'OG004'], 'nonInferiorityType': 'OTHER', 'nonInferiorityComment': 'Difference in percentage based on Miettinen \\& Nurminen method.', 'paramType': 'Difference in Percentage', 'paramValue': '-1.9', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-17.5', 'ciUpperLimit': '13.8', 'estimateComment': 'MK-0616 30 mg minus Placebo'}]}, {'type': 'PRIMARY', 'title': 'Percentage of Participants Who Discontinued Study Intervention Due to AEs', 'description': 'An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The percentage of participants who discontinued study intervention due to AEs was reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'NUMBER', 'unitOfMeasure': 'Percentage of Participants', 'timeFrame': 'Up to approximately 9 Weeks', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '77'}, {'groupId': 'OG001', 'value': '76'}, {'groupId': 'OG002', 'value': '76'}, {'groupId': 'OG003', 'value': '76'}, {'groupId': 'OG004', 'value': '75'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '2.6'}, {'groupId': 'OG001', 'value': '0.0'}, {'groupId': 'OG002', 'value': '2.6'}, {'groupId': 'OG003', 'value': '2.6'}, {'groupId': 'OG004', 'value': '1.3'}]}]}]}, {'type': 'SECONDARY', 'title': 'Percent Change From Baseline in Apolipoprotein B (ApoB) at Week 8', 'description': 'Blood samples were collected at baseline and after 8 weeks of treatment to assess mean percent change in ApoB. The least square mean and 95% CI were obtained from fitting a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time. The percent change from baseline in ApoB at week 8 was reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention, had at least one observation for the analysis endpoint, and had baseline data were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'LEAST\_SQUARES\_MEAN', 'dispersionType': '95% Confidence Interval', 'unitOfMeasure': 'Percentage Change', 'timeFrame': 'Baseline and up to Week 8', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '76'}, {'groupId': 'OG001', 'value': '75'}, {'groupId': 'OG002', 'value': '74'}, {'groupId': 'OG003', 'value': '74'}, {'groupId': 'OG004', 'value': '72'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '-32.8', 'lowerLimit': '-37.6', 'upperLimit': '-27.9'}, {'groupId': 'OG001', 'value': '-45.8', 'lowerLimit': '-50.7', 'upperLimit': '-40.9'}, {'groupId': 'OG002', 'value': '-48.7', 'lowerLimit': '-53.6', 'upperLimit': '-43.8'}, {'groupId': 'OG003', 'value': '-51.8', 'lowerLimit': '-56.7', 'upperLimit': '-47.0'}, {'groupId': 'OG004', 'value': '0.0', 'lowerLimit': '-4.9', 'upperLimit': '4.9'}]}]}], 'analyses': [{'groupIds': ['OG000', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-32.8', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-38.6', 'ciUpperLimit': '-26.9', 'estimateComment': 'MK-0616 6 mg minus Placebo'}, {'groupIds': ['OG001', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-45.8', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-51.7', 'ciUpperLimit': '-39.9', 'estimateComment': 'MK-0616 12 mg minus Placebo'}, {'groupIds': ['OG002', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-48.7', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-54.6', 'ciUpperLimit': '-42.8', 'estimateComment': 'MK-0616 18 mg minus Placebo'}, {'groupIds': ['OG003', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Square Means', 'paramValue': '-51.8', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-57.7', 'ciUpperLimit': '-45.9', 'estimateComment': 'MK-0616 30 mg minus Placebo'}]}, {'type': 'SECONDARY', 'title': 'Percent Change From Baseline in Non-High-density Lipoprotein Cholesterol (Non-HDL-C) at Week 8', 'description': 'Blood samples were collected at baseline and after 8 weeks of treatment to assess mean percent change in non-HDL-C. The least square mean and 95% CI were obtained from fitting a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time. The percent change from baseline in non-HDL-C at week 8 was reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention, had at least one observation for the analysis endpoint, and had baseline data were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'LEAST\_SQUARES\_MEAN', 'dispersionType': '95% Confidence Interval', 'unitOfMeasure': 'Percentage Change', 'timeFrame': 'Baseline and up to Week 8', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '74'}, {'groupId': 'OG001', 'value': '76'}, {'groupId': 'OG002', 'value': '74'}, {'groupId': 'OG003', 'value': '73'}, {'groupId': 'OG004', 'value': '72'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '-34.4', 'lowerLimit': '-39.6', 'upperLimit': '-29.2'}, {'groupId': 'OG001', 'value': '-49.0', 'lowerLimit': '-54.3', 'upperLimit': '-43.7'}, {'groupId': 'OG002', 'value': '-51.8', 'lowerLimit': '-57.1', 'upperLimit': '-46.4'}, {'groupId': 'OG003', 'value': '-54.3', 'lowerLimit': '-59.6', 'upperLimit': '-49.1'}, {'groupId': 'OG004', 'value': '1.5', 'lowerLimit': '-3.9', 'upperLimit': '6.8'}]}]}], 'analyses': [{'groupIds': ['OG000', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-35.9', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-42.4', 'ciUpperLimit': '-29.4', 'estimateComment': 'MK-0616 6 mg minus Placebo'}, {'groupIds': ['OG001', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-50.5', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-57.0', 'ciUpperLimit': '-44.0', 'estimateComment': 'MK-0616 12 mg minus Placebo'}, {'groupIds': ['OG002', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-53.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-59.7', 'ciUpperLimit': '-46.7', 'estimateComment': 'MK-0616 18 mg minus Placebo'}, {'groupIds': ['OG003', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in least squares means based on a cLDA model including terms for treatment, time, baseline statin intensity, baseline renal function, and the interaction of treatment by time.', 'pValue': '<0.001', 'statisticalMethod': 'cLDA', 'paramType': 'Difference in Least Squares Means', 'paramValue': '-55.8', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '-62.3', 'ciUpperLimit': '-49.3', 'estimateComment': 'MK-0616 30 mg minus Placebo'}]}, {'type': 'SECONDARY', 'title': 'Percentage of Participants With LDL-C Value at Goal at Week 8', 'description': 'LDL-C goal was defined as: LDL-C \\<70 mg/dL (\\<1.81 mmol/L) in participants with clinical atherosclerotic cardiovascular disease (ASCVD), LDL-C \\<100 mg/dL (\\<2.59 mmol/L) in participants with an ASCVD risk-equivalent and/or a 10-year risk of having an ASCVD event that is ≥7.5%, OR LDL-C \\<130 mg/dL (\\<3.37mmol/L) in participants with a 10-year risk of having an ASCVD event that is ≥5.0% and \\<7.5%. The percentage of participants with LDL-C value at goal at week 8 were reported.', 'populationDescription': 'All randomized participants who received at least one dose of study intervention and had at least one observation for the analysis endpoint were analyzed.', 'reportingStatus': 'POSTED', 'paramType': 'NUMBER', 'unitOfMeasure': 'Percentage of Participants', 'timeFrame': 'Week 8', 'groups': [{'id': 'OG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG003', 'title': 'MK-0616 30 mg', 'description': 'Participants received 30 mg of MK-0616 orally QD for 8 weeks'}, {'id': 'OG004', 'title': 'Placebo', 'description': 'Participants received MK-0616-matching placebo orally QD for 8 weeks'}], 'denoms': [{'units': 'Participants', 'counts': [{'groupId': 'OG000', 'value': '77'}, {'groupId': 'OG001', 'value': '76'}, {'groupId': 'OG002', 'value': '76'}, {'groupId': 'OG003', 'value': '76'}, {'groupId': 'OG004', 'value': '75'}]}], 'classes': [{'categories': [{'measurements': [{'groupId': 'OG000', 'value': '80.5'}, {'groupId': 'OG001', 'value': '85.5'}, {'groupId': 'OG002', 'value': '90.8'}, {'groupId': 'OG003', 'value': '90.8'}, {'groupId': 'OG004', 'value': '9.3'}]}]}], 'analyses': [{'groupIds': ['OG000', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in percentage based on Miettinen \\& Nurminen method, with sample size weighting, stratified by background statin intensity.', 'pValue': '<0.001', 'statisticalMethod': 'Miettinen & Nurminen', 'paramType': 'Difference in Percentage', 'paramValue': '69.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '56.2', 'ciUpperLimit': '79.0', 'estimateComment': 'MK-0616 6 mg minus Placebo'}, {'groupIds': ['OG001', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in percentage based on Miettinen \\& Nurminen method, with sample size weighting, stratified by background statin intensity.', 'pValue': '<0.001', 'statisticalMethod': 'Miettinen & Nurminen method', 'paramType': 'Difference in Percentage', 'paramValue': '75.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '62.9', 'ciUpperLimit': '84.0', 'estimateComment': 'MK-0616 12 mg minus Placebo'}, {'groupIds': ['OG002', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in percentage based on Miettinen \\& Nurminen method, with sample size weighting, stratified by background statin intensity.', 'pValue': '<0.001', 'statisticalMethod': 'Miettinen & Nurminen method', 'paramType': 'Difference in Percentage', 'paramValue': '79.2', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '67.1', 'ciUpperLimit': '87.1', 'estimateComment': 'MK-0616 18 mg minus Placebo'}, {'groupIds': ['OG003', 'OG004'], 'nonInferiorityType': 'SUPERIORITY', 'nonInferiorityComment': 'One-sided p-value and difference in percentage based on Miettinen \\& Nurminen method, with sample size weighting, stratified by background statin intensity.', 'pValue': '<0.001', 'statisticalMethod': 'Miettinen & Nurminen method', 'paramType': 'Difference in Percentage', 'paramValue': '79.5', 'ciPctValue': '95', 'ciNumSides': 'TWO\_SIDED', 'ciLowerLimit': '67.9', 'ciUpperLimit': '87.4', 'estimateComment': 'MK-0616 30 mg minus Placebo'}]}]}, 'adverseEventsModule': {'frequencyThreshold': '5', 'timeFrame': 'Up to approximately 17 weeks', 'description': 'The population analyzed for the All-Cause Mortality was all randomized participants. The population analyzed for AEs was all randomized participants who received at least one dose of study treatment, corresponding to the study treatment they actually received.', 'eventGroups': [{'id': 'EG000', 'title': 'MK-0616 6 mg', 'description': 'Participants received 6 mg of MK-0616 orally QD for 8 weeks', 'deathsNumAffected': 0, 'deathsNumAtRisk': 77, 'seriousNumAffected': 1, 'seriousNumAtRisk': 77, 'otherNumAffected': 11, 'otherNumAtRisk': 77}, {'id': 'EG001', 'title': 'MK-0616 12 mg', 'description': 'Participants received 12 mg of MK-0616 orally QD for 8 weeks', 'deathsNumAffected': 0, 'deathsNumAtRisk': 76, 'seriousNumAffected': 3, 'seriousNumAtRisk': 76, 'otherNumAffected': 13, 'otherNumAtRisk': 76}, {'id': 'EG002', 'title': 'MK-0616 18 mg', 'description': 'Participants received 18 mg of MK-0616 orally QD for 8 weeks', 'deathsNumAffected': 1, 'deathsNumAtRisk': 76, 'seriousNumAffected': 2, 'seriousNumAtRisk': 76, 'otherNumAffected': 15, 'otherNumAtRisk': 76}, {'id': 'EG003', 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In this case, a coordinating investigator will be designated by mutual agreement. If publication activity is not directed by the Sponsor, the investigator agrees to submit all manuscripts or abstracts to the Sponsor before submission. This allows the Sponsor to protect proprietary information and to provide comments.'}, 'pointOfContact': {'title': 'Senior Vice President, Global Clinical Development', 'organization': 'Merck Sharp & Dohme LLC', 'email': 'ClinicalTrialsDisclosure@merck.com', 'phone': '1-800-672-6372'}}}, 'documentSection': {'largeDocumentModule': {'largeDocs': [{'typeAbbrev': 'Prot\_SAP', 'hasProtocol': True, 'hasSap': True, 'hasIcf': False, 'label': 'Study Protocol and Statistical Analysis Plan', 'date': '2022-05-24', 'uploadDate': '2023-11-15T09:30', 'filename': 'Prot\_SAP\_000.pdf', 'size': 3447418}]}}, 'derivedSection': {'miscInfoModule': {'versionHolder': '2024-06-28'}, 'conditionBrowseModule': {'meshes': [{'id': 'D000006938', 'term': 'Hyperlipoproteinemia Type II'}, {'id': 'D000006937', 'term': 'Hypercholesterolemia'}], 'ancestors': [{'id': 'D000006949', 'term': 'Hyperlipidemias'}, {'id': 'D000050171', 'term': 'Dyslipidemias'}, {'id': 'D000052439', 'term': 'Lipid Metabolism Disorders'}, {'id': 'D000008659', 'term': 'Metabolic Diseases'}, {'id': 'D000008052', 'term': 'Lipid Metabolism, Inborn Errors'}, {'id': 'D000008661', 'term': 'Metabolism, Inborn Errors'}, {'id': 'D000030342', 'term': 'Genetic Diseases, Inborn'}, {'id': 'D000006951', 'term': 'Hyperlipoproteinemias'}], 'browseLeaves': [{'id': 'M9988', 'name': 'Hypercholesterolemia', 'asFound': 'Hypercholesterolemia', 'relevance': 'HIGH'}, {'id': 'M10000', 'name': 'Hyperlipidemias', 'relevance': 'LOW'}, {'id': 'M10002', 'name': 'Hyperlipoproteinemias', 'relevance': 'LOW'}, {'id': 'M9989', 'name': 'Hyperlipoproteinemia Type II', 'asFound': 'Familial Hypercholesterolemia', 'relevance': 'HIGH'}, {'id': 'M26181', 'name': 'Dyslipidemias', 'relevance': 'LOW'}, {'id': 'M11639', 'name': 'Metabolic Diseases', 'relevance': 'LOW'}, {'id': 'M27029', 'name': 'Lipid Metabolism Disorders', 'relevance': 'LOW'}, {'id': 'M11641', 'name': 'Metabolism, Inborn Errors', 'relevance': 'LOW'}, {'id': 'M11054', 'name': 'Lipid Metabolism, Inborn Errors', 'relevance': 'LOW'}, {'id': 'M23686', 'name': 'Genetic Diseases, Inborn', 'relevance': 'LOW'}], 'browseBranches': [{'abbrev': 'BC18', 'name': 'Nutritional and Metabolic Diseases'}, {'abbrev': 'All', 'name': 'All Conditions'}, {'abbrev': 'BC16', 'name': 'Diseases and Abnormalities at or Before Birth'}]}, 'interventionBrowseModule': {'browseLeaves': [{'id': 'M2849', 'name': 'PCSK9 Inhibitors', 'relevance': 'LOW'}], 'browseBranches': [{'abbrev': 'Lipd', 'name': 'Lipid Regulating Agents'}, {'abbrev': 'All', 'name': 'All Drugs and Chemicals'}]}}, 'hasResults': True}, {'protocolSection': {'identificationModule': {'nctId': 'NCT05070390', 'orgStudyIdInfo': {'id': '0616-007'}, 'secondaryIdInfos': [{'id': 'MK-0616-007', 'type': 'OTHER', 'domain': 'Merck'}], 'organization': {'fullName': 'Merck Sharp & Dohme LLC', 'class': 'INDUSTRY'}, 'briefTitle': 'A Study of MK-0616 in Participants With Moderate Renal Impairment (MK-0616-007)', 'officialTitle': 'An Open-Label Clinical Study to Evaluate the Pharmacokinetics of MK-0616 Following Administration of a Single Dose to Participants With Moderate Renal Impairment'}, 'statusModule': {'statusVerifiedDate': '2023-05', 'overallStatus': 'COMPLETED', 'expandedAccessInfo': {'hasExpandedAccess': False}, 'startDateStruct': {'date': '2021-11-16', 'type': 'ACTUAL'}, 'primaryCompletionDateStruct': {'date': '2023-05-03', 'type': 'ACTUAL'}, 'completionDateStruct': {'date': '2023-05-03', 'type': 'ACTUAL'}, 'studyFirstSubmitDate': '2021-10-01', 'studyFirstSubmitQcDate': '2021-10-06', 'studyFirstPostDateStruct': {'date': '2021-10-07', 'type': 'ACTUAL'}, 'lastUpdateSubmitDate': '2023-05-19', 'lastUpdatePostDateStruct': {'date': '2023-05-23', 'type': 'ACTUAL'}}, 'sponsorCollaboratorsModule': {'responsibleParty': {'type': 'SPONSOR'}, 'leadSponsor': {'name': 'Merck Sharp & Dohme LLC', 'class': 'INDUSTRY'}}, 'oversightModule': {'oversightHasDmc': False, 'isFdaRegulatedDrug': True, 'isFdaRegulatedDevice': False}, 'descriptionModule': {'briefSummary': 'This purpose of this study is to compare the pharmacokinetics (PK) of a single dose of MK-0616 in participants with moderate renal impairment (RI) to those of healthy matched control participants. This study is being conducted to assess the impact of moderate renal insufficiency on the PK of MK-0616.'}, 'conditionsModule': {'conditions': ['Moderate Renal Impairment']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE1'], 'designInfo': {'allocation': 'NON\_RANDOMIZED', 'interventionModel': 'SEQUENTIAL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'NONE'}}, 'enrollmentInfo': {'count': 18, 'type': 'ACTUAL'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'Panel A- Moderate RI', 'type': 'EXPERIMENTAL', 'description': 'Single dose of MK-0616 10 mg', 'interventionNames': ['Drug: MK-0616']}, {'label': 'Panel B- Healthy Controls', 'type': 'EXPERIMENTAL', 'description': 'Single dose of MK-0616 10 mg', 'interventionNames': ['Drug: MK-0616']}], 'interventions': [{'type': 'DRUG', 'name': 'MK-0616', 'description': '10 mg capsule administered orally', 'armGroupLabels': ['Panel A- Moderate RI', 'Panel B- Healthy Controls']}]}, 'outcomesModule': {'primaryOutcomes': [{'measure': 'Area Under the Concentration-Time Curve from Time 0 to Infinity (AUC0-Inf) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified timepoints to determine the AUC0-inf of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'AUC from Time 0 to Last Measurable Concentration (AUClast) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified timepoints to determine the AUClast of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'Maximum Plasma Concentration (Cmax) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified time points to determine the Cmax of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'Time to Maximum Plasma Concentration (Tmax) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified time points to determine the Tmax of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'Apparent Terminal Half-life (t1/2) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified time points to determine the t1/2 of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'Apparent Clearance (CL/F) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified time points to determine the CL/F of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}, {'measure': 'Apparent Volume of Distribution (Vz/F) of MK-0616', 'description': 'Blood for plasma samples will be collected at pre-specified time points to determine the Vz/F of MK-0616', 'timeFrame': 'Pre-dose and 1, 1.5, 2, 3, 5, 8, 12, 24, 36, 48, 72, 120, 168, 240, and 336 hours post dose'}], 'secondaryOutcomes': [{'measure': 'Number of Participants Experiencing an Adverse Event (AE)', 'description': 'An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. 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Participants who have had situational depression may be enrolled in the study at the discretion of the investigator.\n\* History of cancer, with the exception of adequately treated nonmelanomatous skin carcinoma or carcinoma in situ of the cervix or other malignancies that have been successfully treated with appropriate follow up and therefore unlikely to recur for the duration of the study.\n\* History of significant multiple and/or severe allergies.\n\* Positive for hepatitis B surface antigen (HBsAg), hepatitis C antibodies or human immunodeficiency virus (HIV).\n\* History of major surgery, donated or lost 1 unit of blood (approximately 500 mL) within 4 weeks prior to the prestudy (screening) visit.\n\* Moderate RI participants: Does not agree to follow the smoking restrictions as defined by the study.\n\* Healthy Matched Controls: History of smoking and/or has used nicotine or nicotine-containing products (eg, nicotine patch and electronic cigarette) within 3 months of screening.\n\* Received any nonlive vaccine starting from 14 days prior to study intervention or is scheduled to receive any nonlive vaccine through 30 days following study intervention with the exception of COVID-19 vaccine administration. Study intervention must be given at least 72 hours following or at least 48 hours prior to any COVID-19 vaccination.\n\* Consumes greater than 3 servings of alcoholic beverages per day.\n\* Consumes excessive amounts, defined as greater than 6 servings (1 serving is approximately equivalent to 120 mg of caffeine) of coffee, tea, cola, energy drinks, or other caffeinated beverages per day.\n\* Regular user of cannabis, any illicit drugs or has a history of drug (including alcohol) abuse within approximately 3 months', 'healthyVolunteers': True, 'sex': 'ALL', 'minimumAge': '18 Years', 'maximumAge': '75 Years', 'stdAges': ['ADULT', 'OLDER\_ADULT']}, 'contactsLocationsModule': {'overallOfficials': [{'name': 'Medical Director', 'affiliation': 'Merck Sharp & Dohme LLC', 'role': 'STUDY\_DIRECTOR'}], 'locations': [{'facility': 'Velocity Clinical Research, Hallandale Beach ( Site 0002)', 'city': 'Hallandale Beach', 'state': 'Florida', 'zip': '33009', 'country': 'United States', 'geoPoint': {'lat': 25.9812, 'lon': -80.14838}}, {'facility': 'Alliance for Multispecialty Research, LLC ( Site 0001)', 'city': 'Knoxville', 'state': 'Tennessee', 'zip': '37920', 'country': 'United States', 'geoPoint': {'lat': 35.96064, 'lon': -83.92074}}]}, 'ipdSharingStatementModule': {'ipdSharing': 'YES', 'description': 'http://engagezone.msd.com/doc/ProcedureAccessClinicalTrialData.pdf', 'url': 'http://engagezone.msd.com/ds\_documentation.php'}}, 'derivedSection': {'miscInfoModule': {'versionHolder': '2024-06-28', 'submissionTracking': {'estimatedResultsFirstSubmitDate': '2024-04-09', 'submissionInfos': [{'releaseDate': '2024-04-09'}]}}, 'conditionBrowseModule': {'meshes': [{'id': 'D000051437', 'term': 'Renal Insufficiency'}], 'ancestors': [{'id': 'D000007674', 'term': 'Kidney Diseases'}, {'id': 'D000014570', 'term': 'Urologic Diseases'}, {'id': 'D000052776', 'term': 'Female Urogenital Diseases'}, {'id': 'D000005261', 'term': 'Female Urogenital Diseases and Pregnancy Complications'}, {'id': 'D000091642', 'term': 'Urogenital Diseases'}, {'id': 'D000052801', 'term': 'Male Urogenital Diseases'}], 'browseLeaves': [{'id': 'M26718', 'name': 'Renal Insufficiency', 'asFound': 'Renal Impairment', 'relevance': 'HIGH'}, {'id': 'M10698', 'name': 'Kidney Diseases', 'relevance': 'LOW'}, {'id': 'M17319', 'name': 'Urologic Diseases', 'relevance': 'LOW'}, {'id': 'M2875', 'name': 'Urogenital Diseases', 'relevance': 'LOW'}, {'id': 'M27093', 'name': 'Female Urogenital Diseases', 'relevance': 'LOW'}, {'id': 'M14127', 'name': 'Pregnancy Complications', 'relevance': 'LOW'}, {'id': 'M8399', 'name': 'Female Urogenital Diseases and Pregnancy Complications', 'relevance': 'LOW'}, {'id': 'M27095', 'name': 'Male Urogenital Diseases', 'relevance': 'LOW'}], 'browseBranches': [{'abbrev': 'BXS', 'name': 'Urinary Tract, Sexual Organs, and Pregnancy Conditions'}, {'abbrev': 'All', 'name': 'All Conditions'}]}}, 'hasResults': False}, {'protocolSection': {'identificationModule': {'nctId': 'NCT05952869', 'orgStudyIdInfo': {'id': '0616-017'}, 'secondaryIdInfos': [{'id': 'MK-0616-017', 'type': 'OTHER', 'domain': 'Merck'}, {'id': '2022-502782-14', 'type': 'REGISTRY', 'domain': 'EU CT'}, {'id': 'U1111-1285-4257', 'type': 'OTHER', 'domain': 'UTN'}], 'organization': {'fullName': 'Merck Sharp & Dohme LLC', 'class': 'INDUSTRY'}, 'briefTitle': 'A Study of MK-0616 (Oral PCSK9 Inhibitor) in Adults With Heterozygous Familial Hypercholesterolemia (MK-0616-017) CORALreef HeFH', 'officialTitle': 'A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-0616 in Adults With Heterozygous Familial Hypercholesterolemia'}, 'statusModule': {'statusVerifiedDate': '2024-03', 'overallStatus': 'ACTIVE\_NOT\_RECRUITING', 'expandedAccessInfo': {'hasExpandedAccess': False}, 'startDateStruct': {'date': '2023-08-08', 'type': 'ACTUAL'}, 'primaryCompletionDateStruct': {'date': '2025-04-28', 'type': 'ESTIMATED'}, 'completionDateStruct': {'date': '2025-04-28', 'type': 'ESTIMATED'}, 'studyFirstSubmitDate': '2023-07-10', 'studyFirstSubmitQcDate': '2023-07-10', 'studyFirstPostDateStruct': {'date': '2023-07-19', 'type': 'ACTUAL'}, 'lastUpdateSubmitDate': '2024-03-12', 'lastUpdatePostDateStruct': {'date': '2024-03-13', 'type': 'ACTUAL'}}, 'sponsorCollaboratorsModule': {'responsibleParty': {'type': 'SPONSOR'}, 'leadSponsor': {'name': 'Merck Sharp & Dohme LLC', 'class': 'INDUSTRY'}}, 'oversightModule': {'oversightHasDmc': True, 'isFdaRegulatedDrug': True, 'isFdaRegulatedDevice': False}, 'descriptionModule': {'briefSummary': 'The goal of this study is to evaluate the efficacy, safety, and tolerability of MK-0616 in adult participants with heterozygous familial hypercholesterolemia. The primary hypothesis is that MK-0616 is superior to placebo on mean percent change from baseline in low-density lipoprotein cholesterol (LDL-C) at Week 24.'}, 'conditionsModule': {'conditions': ['Hypercholesterolemia', 'Familial Hypercholesterolemia']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE3'], 'designInfo': {'allocation': 'RANDOMIZED', 'interventionModel': 'PARALLEL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'TRIPLE', 'whoMasked': ['PARTICIPANT', 'INVESTIGATOR', 'OUTCOMES\_ASSESSOR']}}, 'enrollmentInfo': {'count': 270, 'type': 'ESTIMATED'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'MK-0616', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 20 mg of MK-0616 orally once daily (QD) for up to 52 weeks.', 'interventionNames': ['Drug: MK-0616']}, {'label': 'Placebo', 'type': 'PLACEBO\_COMPARATOR', 'description': 'Participants will receive MK-0616-matching placebo orally QD for up to 52 weeks.', 'interventionNames': 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The primary hypothesis is that MK-0616 is superior to placebo on mean percent change from baseline in low-density lipoprotein cholesterol (LDL-C) at Week 24.'}, 'conditionsModule': {'conditions': ['Hypercholesterolemia', 'Familial Hypercholesterolemia']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE3'], 'designInfo': {'allocation': 'RANDOMIZED', 'interventionModel': 'PARALLEL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'TRIPLE', 'whoMasked': ['PARTICIPANT', 'INVESTIGATOR', 'OUTCOMES\_ASSESSOR']}}, 'enrollmentInfo': {'count': 2760, 'type': 'ESTIMATED'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'MK-0616', 'type': 'EXPERIMENTAL', 'description': 'Participants will receive 20 mg of MK-0616 orally once daily (QD) for up to 52 weeks.', 'interventionNames': ['Drug: MK-0616']}, {'label': 'Placebo', 'type': 'PLACEBO\_COMPARATOR', 'description': 'Participants will receive MK-0616-matching placebo orally QD for up to 52 weeks.', 'interventionNames': 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The primary objective is to evaluate the efficacy of MK-0616 compared with placebo in increasing the time to the first occurrence of major adverse cardiovascular events (MACE) including coronary heart disease (CHD) death, ischemic stroke, myocardial infarction (MI), acute limb ischemia or major amputation, or urgent arterial revascularization.'}, 'conditionsModule': {'conditions': ['Arteriosclerosis', 'Hypercholesterolaemia']}, 'designModule': {'studyType': 'INTERVENTIONAL', 'phases': ['PHASE3'], 'designInfo': {'allocation': 'RANDOMIZED', 'interventionModel': 'PARALLEL', 'primaryPurpose': 'TREATMENT', 'maskingInfo': {'masking': 'TRIPLE', 'whoMasked': ['PARTICIPANT', 'INVESTIGATOR', 'OUTCOMES\_ASSESSOR']}}, 'enrollmentInfo': {'count': 14550, 'type': 'ESTIMATED'}}, 'armsInterventionsModule': {'armGroups': [{'label': 'MK-0616', 'type': 'EXPERIMENTAL', 'description': 'Participants receive MK-0616 20 mg once daily.', 'interventionNames': ['Drug: MK-0616']}, {'label': 'Placebo', 'type': 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Age ≥18 years with a history of a major atherosclerotic cardiovascular disease (ASCVD) event defined as at least 1 of the following: ≥30 days post MI (presumed Type 1 due to plaque rupture or erosion); ≥30 days post ischemic stroke (presumed due to atherosclerosis); or ≥30 days post successful peripheral (carotid or lower extremity) arterial revascularization (surgical or endovascular) or major (ankle or above) amputation due to atherosclerosis; or\n 2. High risk for first major ASCVD event defined as at least 1 of the following: Age ≥50 years with evidence of coronary artery disease; Age ≥50 years with evidence of atherosclerotic cerebrovascular disease; Age ≥50 years with evidence of peripheral arterial disease; or Age ≥60 years with diabetes mellitus and at least one of the following: microvascular disease or urine albumin-creatinine ratio ≥30 mg/mmol within 6 months before Visit 1, daily insulin use, or diabetes for ≥10 years\n\* Has fasted lipid values (evaluated by the Central Laboratory) at Visit 1 (Screening) as follows:\n\n 1. History of major ASCVD Event: LDL-C ≥70 mg/dL (1.81 mmol/L) OR non-HDL-C ≥100 mg/dL (2.59 mmol/L)\n 2. High risk for first major ASCVD Event: LDL-C ≥90 mg/dL (2.33 mmol/L) OR non-HDL-C ≥120 mg/dL (3.11 mmol/L)\n\* Is treated with moderate- or high-intensity statin (± nonstatin lipid-lowering therapy \\[LLT\\]) at Visit 1\n\* Is on a stable dose of all background LLTs (including statin and nonstatin agents) for at least 30 days before Visit 1 (Screening) with no medication or dose changes planned during the participation in the study\n\nExclusion Criteria:\n\n\* Has a history of homozygous familial hypercholesterolemia (FH) based on genetic or clinical criteria, compound heterozygous FH, or double heterozygous FH\n\* Has New York Heart Association Class IV heart failure, last known Left Ventricular Ejection Fraction ≤25% by any imaging method, or had a Heart Failure hospitalization within 3 months before Visit 1 (Screening)\n\* Has recurrent ventricular tachycardia within 3 months prior to randomization\n\* Has a planned arterial revascularization procedure\n\* Is undergoing or previously underwent an LDL-C apheresis program within 3 months before Visit 1 (Screening) or plans to initiate an LDL-C apheresis program\n\* Was previously treated/is being treated with certain other cholesterol lowering medications, including protein convertase subtilisin/kexin type 9 (PCSK9) inhibitors without adequate washout.\n\* Has a fasting triglyceride value ≥400 mg/dL (≥4.52 mmol/L) at Visit 1 (Screening)\n\* Has history of severe renal insufficiency defined as estimated glomerular filtration rate \\<30 mL/min/1.73 m2 at Visit 1 (Screening) or has end-stage renal disease on dialysis.', 'healthyVolunteers': False, 'sex': 'ALL', 'minimumAge': '18 Years', 'stdAges': ['ADULT', 'OLDER\_ADULT']}, 'contactsLocationsModule': {'centralContacts': [{'name': 'Toll Free Number', 'role': 'CONTACT', 'phone': '1-888-577-8839', 'email': 'Trialsites@merck.com'}], 'overallOfficials': [{'name': 'Medical Director', 'affiliation': 'Merck Sharp & Dohme LLC', 'role': 'STUDY\_DIRECTOR'}], 'locations': [{'facility': 'Advanced Cardiovascular - 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