# Clinical Trials Data KIT - Document 64

# Comparative Study of the Immunogenicity of MMR (Measles, Mumps and Rubella) Single Dose and Multidose Presentations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01777529

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Children of both sexes.\n\* Age between 12 and 23 months and 29 days.\n\* Child in good health, without significant personal morbid history, such as genetic syndromes, epilepsy, diabetes, severe infections and immune dysfunctions.\n\* Concordance of the father or mother, or legal guardian, with the child's participation in the study, and signing the Informed Consent Form (ICF).\n\* Disposition of the father or mother, or legal guardian, to provide name, address, telephone number and other information so you can get in touch with this (s) if necessary.\n\* Responsible able understand the risks of the experiment that, although minimal, there.\n\* Responsible able to understand and sign the informed consent form. If the charge is not able to sign (illiterate) the ICF may be signed by an impartial witness who has followed the whole procedure.\n\* Availability return to collect post-vaccination - The subjects of research may not be participating in another clinical trial during this study.\n\* Not having received the vaccine Immunization Schedule in the last 30 days.\n\* Not receiving another vaccine until harvest 2, 42 days after vaccination with MMR.\n\nNon-inclusion criteria\n\n\* Children with a history of measles, rubella and or mumps.\n\* Having previously received MMR vaccination documented in book (eg in situations of conducting national campaign or blocking vaccination before suspected cases of the disease).\n\* Have received injectable vaccines of live attenuated (eg. Yellow fever vaccine) - in this case, defer vaccination with MMR after 30 days of the last live attenuated vaccine administered.\n\* Having received a transfusion of blood or blood products, including immunoglobulins, less than 1 year.\n\* Skin lesions at sites of venipuncture.\n\* Child subject to abnormal bleeding after injections.\n\* Use the last 6 months in immunosuppressive doses of corticosteroids and other immunosuppressants.\n\* Fever or the day of inclusion in the 3 days prior to the inclusion in this case may be rescheduled for inclusion after 14 days the fever subsides.\n\* Use of antibiotic on the day of inclusion or in the last 7 days prior to the date of inclusion - in this case, may be rescheduled for inclusion after 14 days of the last day of antibiotic use.\n\* Any significant abnormality on physical examination the day of enrollment.\n\* Hypersensitivity known systemic neomycin or any other component of the vaccine.\n\* Guy with a history of severe allergy, anaphylaxis to egg proteins",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "12 Months",  
"stdAges": [  
"CHILD"  
]

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided clinical trial information, the eligibility criteria do not mention any specific exclusions regarding gene mutations, including mutations in the KIT gene. The focus of the criteria is primarily on the health status, age, vaccination history, and certain medical conditions and treatments that may impact participation.  
  
Therefore, a patient with a KIT gene mutation would not be automatically excluded from the trial based on the information given, as long as they meet the other inclusion criteria and do not have any of the listed non-inclusion criteria such as significant personal morbidity, immune dysfunctions, or any other specified conditions. However, it is always important to consult with the clinical trial coordinators for confirmation and any additional considerations they might have regarding genetic mutations or other health conditions.