

Terminated/Withdrawn Ketogenic Diet Intervention and Cancer Clinical Trials

Status	Trial ID	Name	Phase	Design	N	Cancer Type	Diet	Length	Treatment	Purpose
Terminated (Recruitment challenges due to competition with another microbiome trial, pt refusal, and poor tolerance of oral DPD)	NCT05119010	A Pilot Study Evaluating a Ketogenic Diet Concomitant to Nivolumab and Ipilimumab in pts With Metastatic Renal Cell Carcinoma (KETOREIN)	N/A	Parallel Assignment	n=3	Renal cell carcinoma	KD: <40 g/day CHO, w/ oral liquid ketone supplement BHB monoester (2 tablespoons three times per day for third arm)	1 year	Immunotherapy	Evaluate the objective response rate (including partial and complete responses) to the combination of Nivolumab and Ipilimumab administered alongside either a ketogenic diet (continuous or intermittent) or a standard diet, with or without beta-hydroxybutyrate (BHB) supplementation.
Terminated (low accrual)	NCT01419483	Ketogenic Diet With Concurrent Chemoradiation for Pancreatic Cancer (KETOPAN)	N/A	Single Group Assignment	n=5	Pancreatic	KD: 4:1 [fat:protein+CHO]	5 weeks	Chemoradiation	Examine the safety and tolerability of KD combined with chemotherapy and radiation therapy in pts with pancreatic cancer.
Terminated (slow recruitment, lack of funding, transferred PI)	NCT00932672	Atkins Diet and Prostate Cancer Clinical Trial	II	RCT	n=45	Prostate	AD: <20 g/day CHO	6 months	Androgen deprivation therapy	Test the hypothesis that low carbohydrate diet will minimize metabolic consequences of androgen deprivation therapy.
Terminated (PI unavailable and pts lost to follow up)	NCT03328858	Ketogenic Diet in Children With Malignant or Recurrent/Refractory Brain Tumor	N/A	Single Group Assignment	n=20	Brain tumor (medulloblastoma, high-grade glioma, low-grade glioma, and ependymoma)	KD: 4:1 [fat:protein+CHO]	1 year	Chemoradiation	Evaluate the effects of KD on QoL and tumor size in pts (pediatric) with malignant or recurrent/refractory brain tumors.
Withdrawn (low accrual)	NCT04231734	Ketogenic Diet in Patients With Untreated	I	Single Group Assignment	n=0	Mantle cell lymphoma	N/A	12 weeks	N/A	To assess the feasibility and adherence to a KD in pts with low tumor

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		Low Tumor Burden Mantle Cell Lymphoma								burden, treatment-naïve mantle cell lymphoma, while monitoring metabolic, tumor, and body composition changes.
Withdrawn (lack of funding)	NCT03955068	Strict Classic Ketogenic Diet as a Therapy for Recurrent or Progressive and Refractory Brain Tumors in Children	N/A	Single Group Assignment	n=0	Brain tumor (regressive or refractory)	KD: 2:1 to 4:1 [fat:protein+CHO] (adjusted based upon BHB levels and compliance)	28 days	N/A	To determine the feasibility of KD of classic, strict KD in pediatric pts with recurrent or progressive and refractory brain tumors and evaluate survival progression and tumor response.
Terminated (poor accrual and pt compliance)	NCT01419587	Ketogenic Diet With Chemoradiation for Lung Cancer (KETOLUNG)	II	Single Group Assignment	n=5	Non-small lung cancer	KD: 4:1 [fat:protein+CHO]	6 weeks	Chemoradiation	Investigate if KD is tolerable and safe when combine with chemotherapy and radiation therapy in pts with lung cancer.
Terminated (excessive protocol deviations due to strict nature of diet requirements)	NCT02046187	Ketogenic Diet With Radiation and Chemotherapy for Newly Diagnosed Glioblastoma	I/II	Single Group Assignment	n=14	Glioblastoma multiforme	KD: 4:1 [fat:protein+CHO] (on chemoradiation), MAD: (on chemotherapy)	8 weeks	Chemoradiation	Evaluates if KD started after surgical resection can be safely maintained and enhance the effectiveness of standard chemoradiotherapy in pts with glioblastoma, and to assess survival, recurrence, and quality of life.
Terminated (low accrual)	NCT01975766	Ketogenic Diet Phase 1 for Head & Neck Cancer	I	Single Group Assignment	n=14	Squamous cell carcinoma	KD: 4:1 [fat:protein+CHO]	5 weeks	Chemoradiation	Determine whether a very low carbohydrate (ketogenic) diet is safe and tolerable for

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										pts undergoing concurrent chemotherapy and radiation therapy for head and neck cancer.
Terminated (low accrual)	NCT03785808	Reducing Insulin, Growth Hormones, and Tumors (RIGHT)	N/A	RCT	n=3	Non-small cell adenocarcinoma, squamous cell carcinoma	KD: 65% fats, starchy vegetables, fruits, berries, and legumes (<10% caloric intake)	24 weeks	N/A	Compare the effects of a low-carbohydrate, high-fat ketogenic diet and a low-fat, high-carbohydrate plant-based diet on biomarkers of inflammation, insulin resistance, and cancer progression in pts with advanced lung cancer.

KD=ketogetic diet

AD=atkin's diet

MAD=modified atkin's diet

CHO=carbohydrate

RCT=randomized controlled trial