

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Therapeutic effect of calorie-Restricted Ketogenic diet on GBM patient's survival and quality of life

Protocol summary

Summary

Glioblastoma multiforme (GBM) is the most common and most aggressive malignant primary brain tumor in humans. Metabolic regimes that use ketolysis in spite of glycolysis may have an inhibitory effect on the growth of GBM cells. Therapeutic effect of Calorie-restricted ketogenic diet on animals has been ascertained. Our goal is to compare the survival and quality of life between two groups of patients. Inclusion criteria: Patient age >49 years, KPS (Karnofsky Performance Scale) >69, had to be operated for brain tumor and Pathology is primary glioblastoma multiforme, has underwent fractionated radiotherapy for his tumor and has received chemotherapy course using Temozolomide and after being treated with surgery, radiotherapy and chemotherapy tumor has recurred. Exclusion criteria includes patients whose Ketogenic diet is contraindicated for them (Pyruvate carboxylase deficiency, Porphyrria and Congenital fat metabolism disorders) and those they cannot tolerate the diet. We include 20 patients in two groups, the intervention and the control group. Intervention group patients will receive the restricted ketogenic Diet. After being admitted in the hospital will receive the ketogenic diet and then be discharged. Control group will not receive the ketogenic diet. Both groups will be followed by Brain MRI and FIM every 3 months as outpatients. Quality of life and survival of both groups will be compared. Age, time recurrence, quality of life as measured by FIM, Time of ketogenic diet and survival are the main factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204099417N1**

Registration date: **2012-04-27, 1391/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-27, 1391/02/08

Registrant information

Name

Ahmad Aoude

Name of organization / entity

Rasoul Azam Hospital

Country

Lebanon

Phone

00982144865961

Email address

aoude79@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-05-31, 1389/03/10

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effect of calorie-Restricted Ketogenic diet on GBM patient's survival and quality of life

Public title

Therapeutic effect of ketogenic diet on survival and quality of patients with Glioblastoma Multiforme

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patient age >49 years 2- KPS (Karnofsky Performance Scale) >69 3- Patient had to be operated for brain tumor and Pathology is primary glioblastoma multiforme 4- Patient has underwent fractionated radiotherapy for his tumor 5- Patient has received chemotherapy course using Temozolomide
Exclusion criteria: 1- Other diagnosis is suspected 2- Patient could not tolerate the ketogenic diet 3- Ketogenic diet is contraindicated (Pyruvate carboxylase deficiency, Porphyria and Congenital fat metabolism disorders) 4- Patient does not agree with the regime protocol

Age

From **50 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university ethics committee

Street address

Keshavarz street, central university building, 6th floor

City

Tehran

Postal code

Approval date

2010-05-30, 1389/03/09

Ethics committee reference number

317\130\89\ص

Health conditions studied

1

Description of health condition studied

Glioblastoma multiforme

ICD-10 code

C71

ICD-10 code description

Malignant neoplasm of brain

Primary outcomes

1

Description

Patient's survival

Timepoint

Every 3 months up to death

Method of measurement

Weeks

Secondary outcomes

1

Description

Quality of Life

Timepoint

Every 3 months

Method of measurement

Assessed by FIM Form

Intervention groups

1

Description

Intervention group: is the group of patients who will receive the restricted ketogenic diet. Patients are admitted in Shariati hospital-neurosurgery ward. Medical history, physical examination, KPS (Karnofsky Performance Scale) and FIM (Functional Independence Measure) will be assessed then routine lab test are performed (CBC, Na, K, Bun, Cr, Fbs, Urine Ketone level). Restricted Ketogenic diet is loaded for them. Blood Sugar and Urine ketone will be checked on daily basis for the 1st week and then weekly. After the regime has been loaded and urine Ketone becomes positive the patient will be informed to use the ketogenic diet and follow the instructions and he would be discharged. Every 3 months a Brain MRI with and without contrast and FIM will be performed for patients. Rerecords of the Urine ketone strips and BS would be controlled for being sure that the regime is effective. Tumor size will be calculated via Brain MRI. Patients will be followed up to their death. patient's Life expectancy and quality of life will be evaluated. Restricted ketogenic diet: • According to patient weight one of the previously designed regimes will be picked to be suitable for the patient. Regimes are designed by a Nutrition specialist and well-matched with 25Kcal/kg. • Before the day of admission in hospital, patient should only drink water and should not eat anything since 6pm. • In the hospital at the 1st day of ketogenic diet loading patient weight will be recorded and suitable regime will be selected. 50% of the

calculated MCT oil (Medium chain triglyceride) according to the patient weight is given in 3 divided meals as Blended MCT oil-Milk, and then the patient is monitored for diarrhea and vomiting. If diarrhea or vomiting occurs the next meal should contain 10% less MCT oil until the patient feel better. Diphenhydramine may be prescribed if needed. • 2nd day: Fasting blood sugar and urine ketone are checked. If the patient has tolerated the diet of the 1st day, he will receive 75% of the calculated MCT oil + 50% of the suitable regime in 3-4 divided meals. • 3rd day: Fasting blood sugar and urine ketone are checked. If the patient has tolerated the diet of the 2nd day, he will receive 100% of the calculated MCT oil + the suitable regime in 5-6 divided meals. • 4th day: Fasting blood sugar and urine ketone are checked. If the patient has tolerated the diet he will be instructed for using the regime and planned for follow up. A multi-vitamin and minerals capsule is prescribed weekly.

Category

Treatment - Drugs

2

Description

Control group contains 10 patients whose will not receive the ketogenic diet

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Ahmad Aoude-Neurosurgery resident

Street address

North Karegar street- Shariati hospital-Neurosurgery ward

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Keshavarz street, Central University building, 5th floor

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Seyyed Mohamad Ghodsi

Position

Neurosurgeon (Associate Professor)

Other areas of specialty/work

Street address

North Karegar street, Shariati hospital, neurosurgery ward

City

Tehran

Postal code

Phone

+98 21 8822 0040

Fax

+98 21 8822 0040

Email

ghodsism@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Seyyed Mohammad Ghodsi

Position

Neurosurgeon (Associate Professor)

Other areas of specialty/work

Street address

North Karegar street, Shariati hospital, Neurosurgery ward

City

Tehran

Postal code

Phone

+98 21 8822 0040

Fax

+98 21 8822 0040

Email

ghodsism@tums.ac.ir

Web page address

+98 21 8822 0040

Email

aoude79@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Ahmad Aoude

Position

Neurosurgery resident

Other areas of specialty/work

Street address

North Kargar Street, shariati Hospital, Neurosurgery
Ward

City

Tehran

Postal code

Phone

+98 21 8822 0040

Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty