

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Metformin plus Temozolamide on Patients with Glioblastoma Multiform

Protocol summary

Summary

The average survival rate for patients with Glioblastoma Multiform is about 12 months, so this study is designed to find a new treatment for these patients. It has been shown that metformin has some antitumoral effect. The study population is the patients with GBM aged 18 and above in both genders with KPS 60 and more into intervention and control groups each one consisted of 30 patients. The patients in intervention group will receive radiotherapy, temozolamide and metformin and the patients in control group will receive radiotherapy, temozolamide and placebo. The survival and progression free survival will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112725256N1**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-04, 1395/05/14

Registrant information

Name

Hossein Eskandary

Name of organization / entity

kerman University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Kerman Neuroscience Institute

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Metformin plus Temozolamide on Patients with Glioblastoma Multiform

Public title

Effect of Metformin on Glioblastoma Multiform

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: GBM diagnosis confirmed by pathology; age>18; KPS>60; normal kidney function exclusion:; no underlining disease which interfere the course of treatment a life threatening diseases other than GBM; DM; infectious disease ; lactation or pregnancy

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Kerman Neuroscience Institute

Street address

Somaie Crossroad in front of Besat Clinic

City

Kerman

Postal code

Approval date

2016-02-18, 1394/11/29

Ethics committee reference number

ir.kmu.rec.1394..371

Health conditions studied

1

Description of health condition studied

Glioblastom multiform

ICD-10 code

C71.9

ICD-10 code description

Brain, unspecified

Primary outcomes

1

Description

overall survival

Timepoint

monthly

Method of measurement

alive or dead

Secondary outcomes

1

Description

progression free survival

Timepoint

based on clinical deterioration

Method of measurement

deterioration of KPS of appearance of new lesion

Intervention groups

1

Description

Intervention Group will receive radiotherapy plus Temozolomide and Metformin 1g daily. The patients should take Metformin durng radiotherapy and after that till primay endpoint.

Category

Treatment - Drugs

2

Description

Control Group will receive radiotherapy and Temozolomide as routine adjuvant treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital

Full name of responsible person

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman Neuroscience Research Center

Full name of responsible person

Vahid Sheibani

Street address

Somayeh Cross- In Front of Besat Clinic

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman Neuroscience Research Center

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*

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Postal code**Phone****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*