

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of low copper diet and penicillamine combination on VEGF, IL-6, IL-8, TNF α and Karnovski performance score in high grade brain glioma after Gamma Knife Radiosurgery in Iran Gamma Knife Center

Protocol summary

Summary

The average survival rate of patients with malignant brain gliomas(GBM) is about 6-11months and this study was designed to find a new way to treat these patients. Copper ion is essential cofactor of angiogenesis and its lead to proliferation of endothelial cells therefore copper depletion inhibits the angiogenic response induced by human brain tumor cells.The study population is patients with glioblastoma multiforme(GBM) aged between 18-65 years in both male and female sex in two intervention and control group and each one consisted of 25 patients.At treatment day,patients based on the main criteria included pathological diagnosis; tumor recurrence; age equal or greater than 18; KPS 60 or more and literacy are classified. in the intervention group, a low copper diet and penicillamine with initial dose of 250 mgr and increased to 1gr and in control group placebo at the same dose will be administered. For control of diet, both groups assess by food frequency questionnaire at the beginning, middle and end of the study. Drug and diet compliance also will be controlled by call. Serum copper concentration will be measured in the time of Baseline and after a month and a half (center study) and at the end of three months (end of study).As the primary outcome factors include VEGF, IL-6, IL-8 , TNF- α and KPS in both groups will be measured at the beginning and end of the study. To investigate the probable side effects of intervention, hemoglobin, WBC, platelet count, creatinine, bilirubin, liver function tests, PT and PTT measure in the beginning, middle and end of the study. Intervention period is considered for 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101415018N1**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-27, 1392/08/05

Registrant information

Name

Alirez Feli

Name of organization / entity

Tehran University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 42933050

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low copper diet and penicillamine combination on VEGF, IL-6, IL-8, TNF α and Karnovski performance

score in high grade brain glioma after Gamma Knife
Radiosurgery in Iran Gamma Knife Center

Public title

Effect of low copper diet and penicillamine combination
on high grade brain glioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pathologic diagnosis; tumor
recurrence; Age equal to or more than 18 years ;KPS
equal to or more than 60 (the status of neurological
function); informed consent;literacy Exclusion criteria:
Avastin (Bevacizumab)use; reduction serum copper to
less than 70 micrograms per deciliter;allergy to penicillin
and penicillamine; pregnancy; Lack of adequate
hematologic, hepatic and renal function

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd,Ghods st.

City

Tehran

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

17241

Health conditions studied

1

Description of health condition studied

Brain tumor

ICD-10 code

C71.9,C72.

ICD-10 code description

Glioblastoma multiforme unspecified site

Primary outcomes

1

Description

Vascular endothelial growth factor

Timepoint

Before and after the intervention.

Method of measurement

How to measure: ELISA, scale: micro mEq per liter

2

Description

Interleukin-6

Timepoint

Before and after the intervention.

Method of measurement

How to measure: ELISA, scale: micro mEq per liter

3

Description

Interleukin-8

Timepoint

Before and after the intervention.

Method of measurement

How to measure: ELISA, scale: micro mEq per liter

4

Description

Tumor Necrosing Factor

Timepoint

Before and after the intervention.

Method of measurement

How to measure: ELISA, scale: micro mEq per liter

5

Description

Karnovski Performance Score(KPS)

Timepoint

Before intervention,one and a half months after the
intervention and at the end of intervention.

Method of measurement

How to measure: clinical, scale:table

Secondary outcomes

1

Description

Drug complications

Timepoint

During the intervention

Method of measurement

Patient quote and physical exam

2

Description

serum copper

Timepoint

Before intervention, one and a half months after the intervention and at the end of intervention.

Method of measurement

How to measure: biochemical, scale: micro gram per deciliter.

Intervention groups

1

Description

Dietary and drug intervention for intervention group. Penicillamine capsule 250 mg every 6 hours, orally for 3 months. Low-copper diet according to table provided to patients for 3 months.

Category

Treatment - Drugs

2

Description

The control group received a placebo capsule of 250 mg orally every 6 hours for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Gamma Knife Center

Full name of responsible person

Alireza Feli

Street address

Dastgerdi martyr St., next to Hazrat Ali Asghar(AS) hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kamrani charity foundation, Iran Gamma Knife Center

Full name of responsible person

Mohsen Bakhtiari

Street address

Dastgerdi Martyr St., next to Hazrat Ali Asghar(AS) hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kamrani charity foundation, Iran Gamma Knife Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

University Research vice chancellor

Full name of responsible person

Mrs. Rostam abadi

Street address

Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University Research vice chancellor

Proportion provided by this source

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

3

Sponsor

Name of organization / entity

Educational Vice Chancellor

Full name of responsible person

Dr. Mohammad javad Hossenzadeh

Street address

Tehran University of Medical Sciences

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Educational Vice Chancellor
Proportion provided by this source
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, School of Nutritional Sciences and Dietetics
Full name of responsible person
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Person responsible for updating data

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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