Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of zinc sulfate supplementation on overall and progression free survival in patients receiving adjuvant chemoradiation for Glioblastoma multiform

Protocol summary

Study aim
Evaluation of overall survival in glioblastoma multi form patients treated with standard protocol with zinc sulfate supplement

Design
A phase 2, randomised clinical trial, with a single group include of 27 patients. Randomize by counting method, enrolled between December 2019 and December 2020, and followed for one year.

Settings and conduct
The sampling method is performed on all of newly diagnosed glioblastoma multiforme patients in Namazi Hospital of Shiraz during one year.All patients enter the study according to the inclusion and exclusion criteria and consume 100 mg of zinc sulfate capsule daily for 8 months at the same time as standard treatment.

Participants/Inclusion and exclusion criteria
Including criteria: New diagnosed glioblastoma multiform patients who proven by pathology Atleast age 18 years old Normal function of the liver, kidneys and hematologic system Without history of other brain diseases Without metastasis Excluding criteria: Unresectable patients Age under 18 years old pregnancy Dysfunction of the liver, kidneys and hematologic system History of other brain diseases Distant metastasis

Intervention groups
Single group treated with Zinc sulfate supplement

Main outcome variables
Overall survival and progress free survival

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190430043432N1**
Registration date: **2019-12-01, 1398/09/10**
Registration timing: **prospective**

Last update: **2019-12-01, 1398/09/10**
Update count: **0**

Registration date
2019-12-01, 1398/09/10

Registrant information

Name
Parisa Kameli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 5233 0772

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parisa.kameli@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of zinc sulfate supplementation on overall and progression free survival in patients receiving adjuvant chemoradiation for Glioblastoma multiform

Public title
zinc sulfate supplementation in Glioblastoma multiform

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New diagnosed patients with glioblastoma multi form
Normal function of liver, kidneys and hematologic system
Normal zinc and cupper serum levels
Exclusion criteria:
Pregnancy History of another malignancy History of allergy to zinc sulfate supplementation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **27**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, opposite Palestine Street, Zand Ave., Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2019-04-13, 1398/01/24
Ethics committee reference number
IR.SUMS.MED.REC.1398.071

Health conditions studied

1

Description of health condition studied
Glioblastoma multiform
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Lifetime from diagnosis to death
Timepoint
Every 3 months to at least 12 months
Method of measurement
Visit the patients and find out if they are alive (Survival Calculation by Week)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intake of 100 mg zinc sulfate supplement capsule daily from the beginning of chemoradiation adjuvant therapy for 30 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazi hospital
Full name of responsible person
Parisa Kameli
Street address
Nemaze Medical Training Center, Nemaze Square, Zand Ave., Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Qasemi
Street address
7th floor, Shiraz University of Medical Sciences, Zand Ave., Shiraz
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+98 71 3212 2430
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Parisa Kameli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data of the study participants, all data potentially shared after unidentifiable individuals.
When the data will become available and for how long
Start access period 10 months after publishing results
To whom data/document is available
Researchers at academic institutes
Under which criteria data/document could be used
Any analysis on the data delivered may be done subject to clarification and permission.
From where data/document is obtainable
parisa.kameli@ymail.com
What processes are involved for a request to access data/document
Please Send me an email with a description of your request for which part of the data and description of the analytics needed. This data E-mailed to you within one week if appropriate.
Comments