

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effects of 5-aminolevulinic acid on the treatment response and the quality of life in the patients with glioblastoma

Protocol summary

Study aim

Effects of 5-aminolevulinic acid on the quality of life in patients with glioblastoma

Design

A randomized controlled clinical trial with parallel, randomized, not blinded groups

Settings and conduct

The study is included 40 patients with glioblastoma referred to Imam Khomeini Hospital, Tehran University of Medical Sciences and Firoozgar Hospital of Iran University of Medical Sciences from September 2019 to September 2020. Patients with multiform glioblastoma are selected based on simple random sampling. Patients are randomly divided into two groups; the conventional treatment with 5-ALA and only the conventional treatments. The first group will receive 5-ALA 5 mg/kg, three hours before radiotherapy in all 30 sessions of radiation therapy. The second group will just receive conventional treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Randomized, obtained written consent, patients with glioblastoma multiforme. Exclusion criteria: Patients with renal and hepatic problems, patients with serious heart diseases, patients with GFR less than 30, patients with immunodeficiency, including AIDS and hepatitis.

Intervention groups

Patients with multiform glioblastoma together the indication of radiotherapy are selected based on simple random sampling. Patients are randomly assigned to two groups; the first group, the conventional treatments together 5-ALA and the second group just the conventional treatments without 5-ALA. Patients in the first group will receive 5-ALA 5 mg/kg, three hours before radiotherapy in all 30 sessions of radiation therapy. And the second group will just receive conventional treatments.

Main outcome variables

Assessments include the quality of life:

General information

Reason for update

Acronym

5-ALA

IRCT registration information

IRCT registration number: **IRCT20140810018745N12**

Registration date: **2019-09-05, 1398/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-05, 1398/06/14**

Update count: **0**

Registration date

2019-09-05, 1398/06/14

Registrant information

Name

Ali Mohammad Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2501

Email address

aalizadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of 5-aminolevulinic acid on the treatment response and the quality of life in the patients with glioblastoma

Public title

Effects of 5-aminolevulinic acid on the quality of life in patients with glioblastoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with written informed consent; randomized; patients with glioblastoma multiforme; patients with KPS above 70 or ECOG 0-1; patients with 30-70 years

Exclusion criteria:

Exclusion criteria: Patients with renal, cardiac, and hepatic problems; Patients with intestinal obstruction; Patients with GFR less than 30; Patients with immunodeficiency such as AIDS and hepatitis; Patients with low white blood cell (less of 1000).

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups; the first group, the standard treatment with 5-ALA and the second group, the standard treatments without 5-ALA. The first group will receive 5-ALA 5 mg/kg, three hours before radiotherapy in all 30 sessions. In the second group, patients will receive just the standard treatments.

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 of Medical Sciences

Street address

Bulvar Keshavarz- Imam Khomaini Hospital

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.115

Health conditions studied

1

Description of health condition studied

Glioblastoma multiforme

ICD-10 code

C71.9

ICD-10 code description

Malignant neoplasm of brain, unspecified

Primary outcomes

1

Description

Quality of life

Timepoint

At the beginning and end of the study

Method of measurement

The questionnaires'

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The case group will receive the 5-ALA drug (5 mg/kg three hours before radiotherapy in all 30 sessions.

Category

Treatment - Drugs

2

Description

Control group: This group will just receive conventional treatments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Research Center, Cancer Institute of IR. Iran,
Imam Khomeini Hospital

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Street address

3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam
Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available