Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the combined effect of temozolomide with nilotinib and temozolomide alone on non-surgical newly diagnosed human glioblastoma multiform tumor: A phase I-II, controlled, placebo, randomized, triple-blinded clinical trial

Protocol summary

Study aim
Determination of advers evvents, survival, and functional status of patients with newly diagnosed glioblastoma treated with temuzolamide regimen and radiotherapy with and without nilotinib

Design
Clinical trial with control group, with parallel groups, triple blind, randomized, phase 1-2, on 20 patients. The block randomization method will be used for randomization.

Settings and conduct
In all patients referred to Shariati Hospital in Tehran (based on inclusion and exclusion criteria), the standard radiation therapy regimen is performed in 30 sessions with a total dose of 60 Gy (2 sessions per session). Also, chemotherapy regimen with temuzolamide (75 mg / m2) will be performed daily during radiation therapy for all patients. Then you will be given a rest for 3 weeks. Temuzolamide capsules (150-200 mg / m2) will then be administered for 5 days in each 28-day cycle for 6 periods. Patients in groups A and B will then receive one of the two capsules of nilotinib 200 mg daily during the chemotherapy phase (28 days per 28-day cycle) or placebo, which will be prescribed in the same way.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age diagnosed with glioblastoma tumor without previous history of surgery, concomitant tumor, renal and hepatic impairment, and immunodeficiency. Pregnant and lactating women will also be excluded.

Intervention groups
Drug group: Nilotinib capsules 200 mg daily during the chemotherapy phase (28 days per 28-day cycle)
Darnama group: The placebo capsule will be prescribed with the same appearance and similar to the drug

Main outcome variables
Side efect of nilotinib

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140120016280N6**
Registration date: **2022-04-16, 1401/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-16, 1401/01/27**
Update count: **0**

Registration date
2022-04-16, 1401/01/27

Registrant information

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Mahmoudreza Hadjighassem
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-09, 1400/12/18

Expected recruitment end date
2023-01-08, 1401/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the combined effect of temozolomide with nilotinib and temozolomide alone on non-surgical newly diagnosed human glioblastoma multiform tumor: A phase I-II, controlled, placebo, randomized, triple-blinded clinical trial

Public title

combined effect of temozolomide with nilotinib and temozolomide alone on newly diagnosed human glioblastoma multiform tumor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 years and more Has newly diagnosis of GBM as determined by MRI findings. Tumors of deep and non-surgical areas Candidate for non-surgical treatment or biopsy

Exclusion criteria:

Age under 18 years Pregnancy Breastfeeding Hepatic or renal dysfunction Infection Concomitant with other brain diseases Existence of metastasis Psychosis and cognitive impairment Autoimmune diseases Patients undergoing brain surgery Ischemic heart disease Receiving other chemotherapy drugs or immunosuppressants during the last three months

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to receive nilotinib or placebo by ratio 1:1. Block randomization through computer-generated codes is performed using Sealed Envelope website (www.sealedenvelope.co) with block size: 4 and list lenght: 20 by researcher who not directly involved in the analysis of the study results. Hence, the randomization sequence will be sealed with same envelopes and provided to main investigator. The schedule will be provided to the Pharma Co. and sealed envelopes containing the treatment allocation of each randomization code will be provided to the main investigator in case of emergency.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Nilotinib and placebo capsules, which are exactly the same in appearance, are prepared by the manufacturer and in the form of A and B capsules by a person (company representative) who only knows the contents of the capsules, is provided to the therapist (radio oncologist). The therapist researcher assigns patients into two groups A and B, using randomized envelopes. The evaluations, data collection, and final analysis will be performed by researchers who are unaware of patients' assignments to drug groups and contents. After the final analysis, the company representative will be asked to specify the contents of the drugs. Therefore, patients, researchers, and the final analyzer do not know about the allocation of patients to treatment groups in this study; hence, the study will be three-blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of National Institute for Medical Research Development

Street address

No. 21, beginning of Besat St., West Fatemi St., National Institute of Medical Research Development of Iran (NIMAD)

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.NIMAD.REC.1400.134

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
In this study, all the adverse event of nilotinib will be recorded based on the Common Terminology Criteria for Adverse Events (CTCAE).
Timepoint
1. Weekly in radiation phase 2. Every four weeks in chemotherapy phase
Method of measurement
Blood tests, including a complete blood cell count, creatinine and blood urea, creatine phosphokinase, and liver function test, echocardiography, and electrocardiogram every

Secondary outcomes

1

Description
Overall survival
Timepoint
Every 4 weeks
Method of measurement
History taking

2

Description
Progression-free survival
Timepoint
Every 3 months
Method of measurement
Brain MRI with contrast

3

Description
Karnofski performance score
Timepoint
Every 4 weeks
Method of measurement
Monthly visit with KPS questionnaire

Intervention groups

1

Description
Intervention group: The standard radiation therapy regimen will be performed in 30 sessions with a total dose of 60 Gy (2 Gy per session). Also, chemotherapy regimen with temuzolamide (75 mg / m2) will be performed daily during radiation therapy for all patients. Then you will be given a rest for 3 weeks. Temuzolamide capsules (150-200 mg / m2) will then be administered for 5 days in each 28-day cycle for 6 periods.Nilotinib capsules 200 mg (Sobhan Oncology Pharma Co.) daily during the chemotherapy phase (28 days in each 28-day cycle).
Category
Treatment - Drugs

2

Description
Control group: The standard radiation therapy regimen will be performed in 30 sessions with a total dose of 60 Gy (2 Gy per session). Also, chemotherapy regimen with temuzolamide (75 mg / m2) will be performed daily during radiation therapy for all patients. Then you will be given a rest for 3 weeks. Temuzolamide capsules (150-200 mg / m2) will then be administered for 5 days in each 28-day cycle for 6 periods. Placebo capsule (prepared by Sobhan Oncology Pharma Co.) with the same appearance and similar to Nilotinib capsule and will be used daily during the chemotherapy phase (28 days in each 28-day cycle) for 6 cycles.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Ehsan Jangholi
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North Kargar St., Jalal Al-Ahmad Intersection, Shariati Hospital
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
President of NIMAD
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Web page address
http://nimad.ac.ir/
Grant name
Grant code / Reference number
۴۰۰۱۴۰۲
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development (NIMAD)
Proportion provided by this source
65
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

2

Sponsor
Name of organization / entity
Sobhan Oncology Pharma
Full name of responsible person
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Email
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Grant name
Grant code / Reference number
۴۰۰۱۴۰۲
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sobhan Oncology Pharma
Proportion provided by this source
35
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Jangholi
Position
Neurosurgen
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Medical doctor

Other areas of specialty/work
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Email
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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
Yes - There is 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

Title and more details about the data/document
The analyzed data will be published in the form of a scientific article. However, basic data can only be provided to specific individuals or organizations in specific cases.

When the data will become available and for how long
Since publication

To whom data/document is available
Researchers and health authorities

Under which criteria data/document could be used
Review by relevant organizations and health decision makers

From where data/document is obtainable
Scientific Officer of Study

What processes are involved for a request to access data/document
Written request to the scientific director of the study

Comments