Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Brain MRI abnormalities in tuberous sclerosis complex before and after treatment

Protocol summary

Study aim
Brain MRI abnormalities in tuberous sclerosis complex before and after treatment
Design
Randomized clinical trial with control group, with parallel groups, single-blinded
Settings and conduct
The present study will be performed on patients diagnosed with tuberous sclerosis complex in neurology and dermatology clinics of the Tabriz University of Medical Sciences. Patients will be randomly divided into intervention and control groups. Study will be single blonded and the patient outcome assessor as well as the study data analyzer will not be aware of the patient grouping.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Definite diagnosis of tuberous sclerosis complex; Age over 2 years; Stable hemodynamic conditions; Consult to participate in the study Exclusion criteria: Incidence of drug reactions; Restriction on the use of Everolimus; Cancer; Infectious Disease; Concurrent use of immunosuppressive drugs
Intervention groups
Intervention group: Everolimus drug in the form of 2.5, 5, 7.5 and 10 lets licensed by Swiss company Novartis which will be prescribed 6 months after diagnosis. The dose of the drug will be based on the patient's condition and the physician's discretion.
Main outcome variables
Volume changes in giant astrocytoma and decrease in the volume of subependymal nodules

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180928041159N2**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **prospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**
Registration date
2020-01-26, 1398/11/06

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-30, 1398/11/10
Expected recruitment end date
2020-02-29, 1398/12/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Brain MRI abnormalities in tuberous sclerosis complex before and after treatment

Public title
MRI results in tuberous sclerosis complex before and after treatment
Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of tuberous sclerosis complex Age over 2 years Stable hemodynamic conditions Consult to participate in the study

Exclusion criteria:

incidence of drug reactions Restriction on the use of Everolimus Cancer Infectious diseases Concurrent use of immunosuppressive drugs

Age

From **2 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using simple randomization method and random number table tool and patient's ID last four number digits.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient outcome assessor as well as the study data analyzer will not be aware of the patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculty of Medicine, Golghasht Street, Daneshgah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.TBZMED.REC.1398.1118

Health conditions studied

1

Description of health condition studied

Brain MRI abnormalities in tuberous sclerosis complex

ICD-10 code

Q85.1

ICD-10 code description

Tuberous sclerosis

Primary outcomes

1

Description

Volume changes in giant astrocytoma

Timepoint

At baseline, 6 months after receiving everolimus

Method of measurement

Magnetic Resonance Imaging

2

Description

Decrease in the volume of subependymal nodules

Timepoint

At baseline, 6 months after receiving everolimus

Method of measurement

Magnetic Resonance Imaging

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Everolimus drug in the form of 2.5, 5, 7.5 and 10 mg tablets licensed by Swiss company Novartis which will be prescribed for 6 months after diagnosis. The dose of the drug will be based on the patient's condition and the physician's discretion.

Category

Diagnosis

2

Description

Control group: This group will no receive any intervention and will be treated as a control group for 6 months and results will compared with intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Emamreza hospital
Full name of responsible person
Dr. Mohammad Hossein Daghighi
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Golghasht Street, Daneshgah Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Leyla Yousefi Halvaie
Position
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Person responsible for updating data

Contact

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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.
When the data will become available and for how long
Access to study data after publication of the result is available in the journal.
To whom data/document is available
Anyone interested in using the data can access the study data.
Under which criteria data/document could be used
Study data can be used for comparison with other results.
From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.
What processes are involved for a request to access data/document
The use request will be emailed to the scientific or public accountability person.
Comments