

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 blinded 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

Name

Sajjad Pourasghary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3667 0577

Email address

pourasghary.s@umsu.ac.ir

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

Street address

Golghasht Street, Daneshgah Street

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Phone

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imamrezahospital@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hojjat Pourfathi

Street address

Faculty of Medicine, Near Emamreza Hospital,
Golghasht Street, Daneshgah Street

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Email

info@medfac.tbzmed.ac.ir

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

Clinical Assistant of Radiology

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Daghighi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Radiology

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sajjad Pourasghary

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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