

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3337 0574

**Email**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614743

**Phone**

+98 41 3337 6923

**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

**Street address**

Faculty of Medicine, Golghasht Street, Daneshgah  
Street

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liyousefi511@gmail.com

## 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

**Street address**

Urjans Street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

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**Phone**

+98 41 3667 0577

**Fax****Email**

pourasghary.s@umsu.ac.ir

**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**