

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Everolimus on Renal, Brain, Skin Lesions and Seizure of Tuberous Sclerosis Complex

Protocol summary

Study aim

The evaluation and comparison of the brain, renal, skin lesions, and seizure severity in the TSC patients before and after 6 months of everolimus treatment.

Design

20 eligible children, age under 15 years with TSC will include in this study after obtaining consent. A code was allocated to each one of them.

Settings and conduct

TSC patients referring to the Neurology Clinic of Tabriz Children Hospital after including in the study, brain, renal, skin lesions, and seizure severity will be evaluated in the patients by standard methods. Based on the references, 3 mg/m²/day of everolimus will be administered to the patients for 6 months. The patients will be evaluated for any probable side effect of the drug during the administration period. After six months of the treatment, the severity of the lesions will be evaluated again by the standard methods and will be statistically compared with the basal severity of the lesions.

Participants/Inclusion and exclusion criteria

20 Children with TSC, age under 15 years that referred to Neurology Clinic of Tabriz Children Hospital will purposefully be chosen and included in the study after the diagnosis and confirmation of the TSC disease by a medical specialist and getting informed consent. The patients with underlying diseases and or with drug prohibition will be excluded from the study.

Intervention groups

Based on the references, 3 mg/m²/day of everolimus will be administered to the patients for 6 months. The patients will be evaluated for any probable side effect of the drug during the administration period.

Main outcome variables

The results of this study can be considered as an important step in controlling and treating TSC. If the positive therapeutic effect of everolimus on TSC-associated lesions is proven; this drug could also be used in the treatment process of the TSC.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131012014988N2**

Registration date: **2017-12-05, 1396/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-05, 1396/09/14**

Update count: **0**

Registration date

2017-12-05, 1396/09/14

Registrant information

Name

Mohammad Barzegar

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2265

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phrc_mb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Pediatric Health Research Center, Tabriz University of Medical Sciences.

Expected recruitment start date

2017-07-04, 1396/04/13

Expected recruitment end date

2018-01-03, 1396/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Everolimus on Renal, Brain, Skin Lesions and Seizure of Tuberous Sclerosis Complex

Public title

The Effect of Everolimus in the Treatment of Tuberous Sclerosis Complex

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20 children, age under 15 years, with TSC proven by an expert physician through clinical and paraclinical criteria will include in this study Parental consent of the patients

Exclusion criteria:

Having any underlying disease Drug prohibition

Age

To 15 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Regional Ethics Committee, Office of the Vice Chancellor for Research, Tabriz University of Medical

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, PO Box: 5165665931, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2017-07-03, 1396/04/12

Ethics committee reference number

IR.TBZMED.REC.1396.287

Health conditions studied**1****Description of health condition studied**

Tuberous sclerosis

ICD-10 code

Q85.1

ICD-10 code description

Other congenital malformations

Primary outcomes**1****Description**

Renal lesions severity

Timepoint

before treatment-six months after the treatment

Method of measurement

MRI, Medical ultrasound (sonography), questionnaire

2**Description**

Brain lesions severity

Timepoint

before treatment-six months after the treatment

Method of measurement

MRI, Medical ultrasound (sonography), questionnaire

3**Description**

Skin lesions severity

Timepoint

before treatment-six months after the treatment

Method of measurement

Medical examination, questionnaire

4**Description**

Seizure

Timepoint

before treatment-six months after the treatment

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

constipation

Timepoint

During the six months of the administration period

Method of measurement

Clinical Examination, Questionnaire

2

Description

nausea

Timepoint

During the six months of the administration period

Method of measurement

Clinical Examination, Questionnaire

3

Description

diarrhea

Timepoint

During the six months of the administration period

Method of measurement

Clinical Examination, Questionnaire

4

Description

vomiting

Timepoint

During the six months of the administration period

Method of measurement

Clinical Examination, Questionnaire

5

Description

Body weight

Timepoint

During the six months of the administration period

Method of measurement

Scale, Questionnaire

Intervention groups

1

Description

In the case (intervention) group, based on the scientific references, 3 mg/m²/day "Everolimus" (C53H83NO14), in 5 mg tablet form (Novartis Co, Swiss), will administer for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr Mohammad Barzegar

Street address

Tabriz Children Hospital, Sheshgelan Street, Tabriz, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Barzegar

Street address

Pediatric Health Research Center, Tabriz Children Hospital, Sheshgelan Street, Tabriz, Iran.

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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

Pediatric Health Research Center, 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

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Barzegar

Position

Pediatric neurologist, Professor, Faculty Member

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz Children Hospital

Full name of responsible person

Dr Hassan Bakhtiari

Position

Pediatric neurology fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Moahhamad Barzegar

Position

Pediatric Neurologist

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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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