

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of efficacy of Tacrolimus 0.03% ointment with Mometason ointment in treatment of pediatric Atopic Dermatitis

#### Protocol summary

##### Study aim

Comparison of therapeutic effect of Tacrolimus 0.03% ointment and Mometason ointment in the treatment of Atopic Dermatitis in children.

##### Design

This is a randomised, double \_ blind, parallel \_ group, controlled phase 3 study. In this study, 30 children with Atopic Dermatitis will be randomly divided into two groups of 15 in each, using Rand List software. The control group will receive Mometason ointment and intervention group will receive Tacrolimus 0.03% ointment.

##### Settings and conduct

Thirty children with Atopic Dermatitis who will refer to Sina Hospital Dermatology clinic will randomly be assigned into two groups of 15 subjects. Intervention group (Tacrolimus 0.03% ointment) and the control group (Mometason ointment).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: children 2-10 years old, children with lesion size up to 5 cm, children with limb lesions, children with mild to moderate lesions, children whose parents declare their full written informed consent to participate in this study. Exclusion criteria: children who have other skin conditions at the same time, children whose skin lesions are infected.

##### Intervention groups

Intervention group: Topical tacrolimus 0.03% ointment. In the intervention group, 15 children with Atopic Dermatitis will be treated with Tacrolimus 0.03% ointment every 12 hours for 6 weeks. Control group: topical Mometason ointment. In the control group 15 children with Atopic Dermatitis will be treated with Mometason ointment every 12 hours for 6 weeks.

##### Main outcome variables

Atopic Dermatitis lesions severity index, size of Atopic Dermatitis, patients symptoms, possible complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091012002581N6**

Registration date: **2019-11-25, 1398/09/04**

Registration timing: **prospective**

Last update: **2019-11-25, 1398/09/04**

Update count: **0**

##### Registration date

2019-11-25, 1398/09/04

##### Registrant information

##### Name

Hamide Herizchi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 4650

##### Email address

herizchih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-06, 1398/09/15

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of efficacy of Tacrolimus 0.03% ointment with Mometason ointment in treatment of pediatric Atopic Dermatitis

## Public title

Comparison of efficacy of Tacrolimus 0.03% ointment with Mometason ointment in treatment of pediatric Atopic Dermatitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children 2-10 years old. Children whose lesion are up to 5 cm in size. Children with limb lesions. Children whose parents declare their full written informed consent to participate in this study. Children with mild to moderate lesions.

### Exclusion criteria:

Children who have other skin conditions at the same time. Children whose skin lesions are infected.

## Age

From **2 years** old to **10 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple randomization will be carried out on an individual basis by Rand List software. The allocation will be sealed by an independent monitor and will not be broken until the end of the study.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The investigator assessing outcome and analyzing the data will be blinded to treatment allocation until the end of the study.

## 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

Daneshgah

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5142954481

### Approval date

2019-11-11, 1398/08/20

### Ethics committee reference number

IR.TBZMED.REC.1398.811

## Health conditions studied

## 1

### Description of health condition studied

Atopic Dermatitis

### ICD-10 code

L20

### ICD-10 code description

Atopic dermatitis

## Primary outcomes

## 1

### Description

Atopic Dermatitis lesions severity index

### Timepoint

Weeks 0, 3, 6

### Method of measurement

Observation

## 2

### Description

Size of Atopic Dermatitis lesion

### Timepoint

Weeks 0, 3, 6

### Method of measurement

Ruler measurement

## 3

### Description

Patient symptoms

### Timepoint

Weeks 0, 3, 6

### Method of measurement

Questionnaire

## Secondary outcomes

## 1

### Description

Possible complications

### Timepoint

Weeks 0, 3, 6

### Method of measurement

Observation \_ questionnaire

## Intervention groups

## 1

### Description

Intervention group: Topical Tacrolimus 0.03% ointment.in the intervention group,15 childs with Atopic Dermatitis will be treated with Tacrolimus 0.03% ointment every 12 hours for 6 weeks.

### Category

Treatment - Other

## 2

### Description

Control group: Topical Mometason ointment.in the control group 15 childs with Atopic Dermatitis will be treated with Mometason ointment every 12 hours for 6 weeks.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Sina Hospital

#### Full name of responsible person

Dr Hamideh Herizchi Ghadim

#### Street address

Azadi Street

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5163639888

#### Phone

+98 41 8236 3549

#### Fax

+98 41 8406 3549

#### Email

Drherizchi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

### Full name of responsible person

Dr. Ataa Mahmoudpour

### Street address

Azadi Street

### City

Tabriz

### Province

East Azarbaijan

### Postal code

5163639888

### Phone

+98 41 8236 3549

### Email

Drherizchi@yahoo.com

### 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 Hamide Herizchi Ghadim

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

#### Street address

Azadi

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5163639888

#### Phone

+98 41 8236 3549

#### Email

Drherizchi@yahoo.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Hamide Herizchi Ghadim

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Azadi

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Phone**

+98 41 8236 3549

**Email**

Drherizchi@yahoo.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sedighe Jafari Majd

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Azadi

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Phone**

+98 41 8236 3549

**Email**

sjafarimajd@gmail.com

## **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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data will be shared after being unidentified.

**When the data will become available and for how long**

All any time

**To whom data/document is available**

It will be free for every one.

**Under which criteria data/document could be used**

There are no special conditions.

**From where data/document is obtainable**

Email: Drherizchi@yahoo.com, 09141168780, Dr Hamide Herizchi Ghadim, Dermatology Department - Sina Hospital - Azadi sreet - Tabriz.

**What processes are involved for a request to access data/document**

The request will be checked, then data will be sent by Email in 1 month.

**Comments**