Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 childs with Atopic Dermatitis will be randomly divided in to two groups of 15 in each, using Rand List software.The control group will recieve Mometason ointment and intervention group will recieve Tacrolimus 0.03% ointment.

Settings and conduct

Thirty childs with Atopic Dermatitis who will refer to Sina Hospital Dermatology clinic will randomly be assigned in to 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 childs 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 childs 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 seated 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