

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the efficacy of combined therapy with topical azathioprine and betamethasone emollient cream versus monotherapy with topical betamethasone emollient cream in 2-18 year-old patients with moderate to severe atopic dermatitis.

Protocol summary

Summary

Objectives: To compare the efficacy of topical azathioprine-betamethasone emollient cream with betamethasone emollient cream for moderate to severe cutaneous lesions of atopic dermatitis. Design: Randomized, single-blind, clinical trial. Setting and Conduct: 70 Patients whose clinical SCORAD index is greater than 25, divide in two groups and receive topical azathioprine- betamethasone cream (case group) and betamethasone cream (control group). Outcome measures will be assessed at baseline, 8th week and one month after the completion of the treatment. In addition, the patients will be examined for any potential adverse effects at the end of the first week of the treatment course. Finally the rate of variation in SCORAD index before and after treatment will be evaluated. Major Inclusion and Exclusion criteria: Inclusion criteria: patients in the range of 2-18 years old; patients with no enough response to conventional topical therapies in recent past 6 months; patients who do not receive any systemic drug which interacts with azathioprine in recent past 1 month; patients with out any liver and bone marrow dysfunction. Exclusion criteria: any laboratory abnormality. Intervention: Patients receive topical treatment twice daily for 8 weeks for cutaneous lesions of the total body other than face (case group : azathioprine-betamethasone, control group : betamethasone).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092519292N1**

Registration date: **2014-11-14, 1393/08/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-14, 1393/08/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Isfahan University of Medical Sciences.

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of combined therapy with topical azathioprine and betamethasone emollient cream versus monotherapy with topical betamethasone emollient cream in 2-18 year-old patients with moderate

to severe atopic dermatitis.

Public title

Efficacy of topical azathioprine-betamethasone cream with betamethasone cream in cutaneous eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children older than 2 years; patients with no enough response to conventional topical therapies in recent past 6 months; patients who do not receive any systemic drug which interacts with azathioprine in recent past 1 month; patients whose lesions are not limited to the face; patients with out any liver and bone marrow dysfunction. Exclusion criteria: any laboratory abnormality; patients who do not desired to stay in the study.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

Isfahan

Postal code

Approval date

2014-09-07, 1393/06/16

Ethics committee reference number

393464

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20.9

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

Clinical severity of cutaneous lesions

Timepoint

At baseline, at the end of the treatment course(8th week), one month after the cessation of the treatment.

Method of measurement

SCORAD index

Secondary outcomes

1

Description

Recurrence of cutaneous lesions

Timepoint

1 month after the cessation of the treatment

Method of measurement

Physical exam and history taking

Intervention groups

1

Description

Patients in intervention group should use the azathioprine-betamethasone emolient cream twice daily for 8 weeks on cutaneous lesions of the whole body except for face.

Category

Treatment - Drugs

2

Description

Patients in control group should use betamethasone emolient cream twice daily for 8 weeks on all cutaneous lesions of the body except for face.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of dermatology of Al Zahra Hospital
Full name of responsible person
Dr Sadaf Farhadi
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Hezar jerib Avenue, Isfahan
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2

Recruitment center

Name of recruitment center
Noor and Aliasghar Hospital
Full name of responsible person
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3

Recruitment center

Name of recruitment center
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Full name of responsible person
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Khorram Street, Johouri Square, Isfahan.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Isfahan University of Medical Sciences
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Deputy of Research of Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan.
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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

Vice Chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty