

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effect of sertaconazole cream with Hydrocortisone ointment on atopic dermatitis in children under five years

Protocol summary

Study aim

A comparison between the therapeutic effect of sertaconazole and hydrocortisone cream on mild-to-moderate atopic dermatitis

Design

The study consists of two groups of parallel and double-blind. Both the clinical researcher and patient were blind to the study. The study samples (76 patients) received drugs A and B in the order of their visit.

Settings and conduct

Children younger than 5 years and with atopic dermatitis are visited in Yasuj's Imam Sajjad Pediatric Clinic. After determining the severity of their disease, WRT, and the type of clinical presentation, the patients with severe involvement are excluded. For the patients with mild-to-moderate skin involvement, the medication is prescribed as types A and B. Medicine efficiency is examined on days 14 and 30 after starting the medication by a physician. Next, with some indicators from previous studies and current valid references, improvement percentages are determined and the two medicines are compared. The clinical researcher and patient are blind to drug type and packaging.

Participants/Inclusion and exclusion criteria

The population of this study consists of children younger than 5 years with atopic dermatitis referred to Yasuj's Imam Sajjad Pediatric Clinic with mild to moderate involvement. The participated in the study after granting their parent's approval. Also, those with severe skin involvement or without parental consent were excluded.

Intervention groups

The intervention group (patients with mild and severe atopic dermatitis) received sertaconazole cream in this intervention. The control group (patients with mild and moderate atopic dermatitis) received hydrocortisone cream in this intervention.

Main outcome variables

primary outcome :skin redness relief measured by examination;secondary outcome 1: skin pruritus relief

measured by a questionnaire;secondary outcome 2: skin dryness relief measured by examination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043996N1**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **retrospective**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

Fatemeh Jokar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3721 0042

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-01, 1398/03/11

Expected recruitment end date

2019-09-17, 1398/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of sertaconazole cream with Hydrocortisone ointment on atopic dermatitis in children under five years

Public title

The effect of the sertaconazole cream with ointment Hydrocortisone in atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children under five years with atopic medium or mild dermatitis

Exclusion criteria:

The lack of parental consent Atopic dermatitis with severe involvement of the skin

Age

To 5 years old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

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

Double blinded

Blinding description

- The patients were initially briefed on the method and type of medication and safety of both medicines; however, it was just drugstore that knew the type of medicine in packages A and B, while the physician and patients were unaware of it. Indeed, the patient and doctor were blind to the drug type.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee university of Medical Sciences, Yasuj

Street address

Street Saheli, The hospital and clinic of Imam Sajjad

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7541994579

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IR.YUMS.REC.1398.029

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**

Medication type

Timepoint

The primary visit is at the beginning of the study before initiating the therapy. The second, third, and fourth visits were made two weeks, one month, and six months after the start of the treatment, respectively.

Method of measurement

Measuring variables involved three visits and patient examination by clinical research at a specified time, as well as completing a questionnaire and table relating to the symptoms. The questionnaire and table of symptoms were derived from previous valid articles and scientific references.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention 1: 2% sertaconazole cream, topical antifungal at a dose of the size of the skin involved two times a day for two weeks, topical application on the skin by hand, Farer International SA Manufactory available at Yasuj's drug stores

Category

Treatment - Drugs

2

Description

Intervention 2: 1% hydrocortisone ointment, low effect topical corticosteroids at a dose of the size of the skin coverage of the affected area two times a day for two weeks, topical application on the skin by hand, Behvarzan Manufactory, Rash, Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam sajjad hospital and clinic

Full name of responsible person

Fazel Ali

Street address

Emamat bulvar

City

Yasuj

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Kohgilouyeh-va-Boyrahmad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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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

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Fazel Ali

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Allergist and clinical immunology

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Person responsible for scientific inquiries

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Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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Latest degree

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Other areas of specialty/work

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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