Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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 sever 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
Kohgilouyeh-va-Boyrahmad
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

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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
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Person responsible for updating data

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Position

Assistant specialized children

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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