

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison between effects of clotrimazole and terbinafine on diaper rash in children

Protocol summary

Study aim

Comparison of the effects of clotrimazole and terbinafine on the improvement of children's beard diaper

Design

This study was a double-blind, double-blind, clinical trial of children with diaphragm.

Settings and conduct

This study was conducted in Kashan Shahid Beheshti Hospital. After obtaining informed and written informed consent, the checklist, including demographic characteristics, lesion area, extent of the lesion per cm, the duration of the onset of dermatitis and the onset of recovery after the administration of the drug are completed.

Participants/Inclusion and exclusion criteria

Entry requirements: Children under the age of two, diagnosis of diaper rash by a pediatrician. Exit conditions: The presence of associated illnesses, such as psoriasis, zinc deficiency, drug allergy to the drugs studied

Intervention groups

Patients are divided into two groups of clotrimazole and terbinafine.

Main outcome variables

Dermestid

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121017011145N21**

Registration date: **2019-06-11, 1398/03/21**

Registration timing: **retrospective**

Last update: **2019-06-11, 1398/03/21**

Update count: **0**

Registration date

2019-06-11, 1398/03/21

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between effects of clotrimazole and terbinafine on diaper rash in children

Public title

Effects of clotrimazole and terbinafine on diaper rash in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children under the age of two, Diagnosis of diaper rash

by pediatrician,

Exclusion criteria:

The presence of associated illnesses such as psoriasis, Zinc deficiency, Drug allergy to the drugs studied,

Age

From **1 day** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Random unit: Individual Randomization Tool: Random Number Tables

Blinding (investigator's opinion)

Not 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 Kashan University of Medical Sciences

Street address

Kashan University of medical sciences, Qotbe Ravand blvd,

City

Kashan

Province

Isfahan

Postal code

8711111111

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.015

Health conditions studied

1

Description of health condition studied

diaper rash

ICD-10 code

L22

ICD-10 code description

Diaper dermatitis

Primary outcomes

1

Description

The extent of the diaphragmatic lesion of children's beech in cm

Timepoint

The effect of clotrimazole and terbinafine on the start of the study and follow up 7 days later

Method of measurement

Measuring questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: clotrimazole and terbinafine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Besheshti hospital

Full name of responsible person

Alireza Salimian Rizi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan 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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Alireza Salimian Rizi

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information will be shared after analyzing and publishing the article.

When the data will become available and for how

long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

After publishing the results, the document can be used.

From where data/document is obtainable

Email to the responsible author

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

After receiving the request, it will be answered.

Comments