Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of topical cholestyramine and zinc oxide in the treatment of diaper dermatitis from diarrhea: a randomized, double-blind clinical trial.

Protocol summary

Study aim
Evaluation of Topical cholestyramine versus topical zinc oxide in treatment of diaper rash

Design
A controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 70 patients. The Excel software rand function will be used for randomization.

Settings and conduct
This project will take place at Shahid Sadoughi hospital in Yazd. Patients in two groups of 35 people use cholestyramine or zinc oxide cream twice a day for 5 days

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diaper dermatitis in children with diarrhea; Age below 2 years. Exclusion criteria: skin or kidney diseases, birth defects, oral or genital candidiasis; using other drugs to treat diaper dermatitis; using topical antibiotics in the area of diaper dermatitis

Intervention groups
In order to investigate the effectiveness of topical cholestyramine in diaper dermatitis, 35 people in the intervention group received topical cholestyramine cream twice a day for 5 days. In the control group, 35 people received topical zinc oxide twice a day for 5 days.

Main outcome variables
Erythema intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181208041882N19**
Registration date: **2023-11-05, 1402/08/14**
Registration timing: **retrospective**

Last update: **2023-11-05, 1402/08/14**
Update count: **0**

Registration date
2023-11-05, 1402/08/14

Registrant information

Name
behrooz heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 8699

Email address
b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of topical cholestyramine and zinc oxide in the treatment of diaper dermatitis from diarrhea: a randomized, double-blind clinical trial.

Public title
The effect of topical cholestyramine in the treatment of diaper dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age less than 24 months Diaper dermatitis in children

with diarrhea

Exclusion criteria:

Skin diseases, kidney diseases, birth defects, oral or genital candidiasis Use of other drugs to treat diaper dermatitis Use of topical antibiotics in the area of diaper dermatitis

Age

To **24 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 70 patients were randomly assigned to two treatment groups A and B. For random allocation, block random allocation method was used. In this study, 10 blocks of size 7 were considered. The generated permutations include letters A and B that are repeated. These permutations were produced with the help of Random allocation software version 1. For this purpose, the list prepared by the software is from number 1 to 70, which are placed in 10 blocks of size seven. To implement this software output, we will give the first qualified person number 1 and the last person will receive number 70.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the physician, and the assessor of clinical symptoms will be all blinded to the intervention’s assignments during performing the study. In this way, the first executor of the sequence plan determines the allocation of individuals according to the order in which patients enter the study and puts Cholestyramine and zinc oxide cream (the same in terms of color and smell) in the same shape boxes for patient consumption. And identifies them with codes A or B. The student then delivers the appropriate medications to the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.196

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

Erythema severity

Timepoint

Days one, three and five after the intervention

Method of measurement

Based on scoring the severity of diaper dermatitis scale

Secondary outcomes

1

Description

Patients' recovery compared to the first day of intervention

Timepoint

The first, third and fifth day after intervention

Method of measurement

Observation and comparison of erythema severity, extent of dermatitis and clinical manifestations

Intervention groups

1

Description

Intervention group: 5% cholestyramine cream formulation (manufactured in Yazd Faculty of Pharmacy),

use topically after each diaper change for 5 days

Category

Treatment - Drugs

2

Description

Control group: Topical zinc oxide ointment 20% (Caspian Company), applied topically after each diaper change for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric ward; Shahid Sadoughi hospital

Full name of responsible person

Behrooz Heydari

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Shahid Sadoughi hospital, Ebnesina Blvd, Shahid Ghandi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abarghouei

Street address

Shahid Sadoughi University of Medical Sciences; Shohadaye Gomnan Blvd; Alem Sq

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abargouei@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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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

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

After making individuals unrecognizable, all data can be shared

When the data will become available and for how long

Six months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

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

Request your information by email. The data will be sent after a week.

Comments