

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of Topical curcumin versus topical zinc oxide in treatment of diaper rash

Protocol summary

2023-10-29, 1402/08/07

Study aim

Evaluation of Topical curcumin versus topical zinc oxide in treatment of diaper rash

Design

A controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 44 patients. The randomization tool of the graphpad.com/quickcalcs/randMenu website was used for randomization

Settings and conduct

This project will take place at Shahid Sadoughi hospital in Yazd. Patients in two groups of 22 people use curcumin or zinc oxide cream twice a day for 5 days

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged less than 2 years; diagnosed with diaper dermatitis. Exclusion criteria: Secondary infectious dermatitis; Use of any corticosteroid; A history of atopic dermatitis, candidiasis, or seborrheic dermatitis; Birth defect

Intervention groups

In order to evaluate the effectiveness of topical curcumin in diaper rash, we give a group of 22 people with curcumin and a group of 22 people with a zinc oxide.

Main outcome variables

Erythema intensity, Erythema extent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N18**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **retrospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

Registration date

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

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Topical curcumin versus topical zinc oxide in treatment of diaper rash

Public title

Topical curcumin compared topical zinc oxide in treatment of diaper rash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged less than 2 years Diagnosed with diaper dermatitis

Exclusion criteria:

Secondary infectious dermatitis Use of any corticosteroid
A history of atopic dermatitis, candidiasis, or seborrheic
dermatitis Birth defect

Age

To 2 years old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: 44

Randomization (investigator's opinion)

Randomized

Randomization description

Forty-four of screened patients met the inclusion criteria. These were randomly allocated to the intervention group (n=22) and control group (n=22) using an online randomization tool: graphpad.com/quickcalcs/randMenu. Then the same numbered curcumin or Zinc Oxide containers were given to the caregivers for use in the intervention and control groups. One of the researchers (Behrooz Heydari) was responsible for this assignment and was the only member aware of randomization and allocation. He did not participate in the evaluation of outcomes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 44 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 10 blocks of 5 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 44 is in 10 blocks of five in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 44.

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

2019-05-18, 1398/02/28

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.082

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

Evaluation of 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: After 2% curcumin cream
formulation, 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

Shahid Sadoughi hospital- pediatric yard

Full name of responsible person

Behrooz Heydari

Street address

Shahid Sadoughi hospital, Ebnesina Blvd, Shahid Ghandi Blvd

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+98 35 3822 4000

Email

b.heydari@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Houshang Mehrparvar

Street address

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Email

ah.mehrparvar@gmail.com

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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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 nonrecognition, all data can be shared

When the data will become available and for how long

6 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