

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the Effectiveness of Topical N-Acetylcysteine and Zinc Oxide in the Treatment of Diaper Dermatitis

Protocol summary

Study aim

Comparison of the Effectiveness of Topical NAC and Zinc Oxide in the Treatment of Diaper Dermatitis

Design

A double-blind randomized controlled clinical trial phase 3 with a parallel-group design of 44 patients.

Randomized by using an online tool
:graphpad.com/quickcalcs/randMenu

Settings and conduct

This study was performed in the pediatric ward of Shahid Sadoughi Hospital in Yazd on patients less than 2 years old with diaper dermatitis. Patients who met the inclusion criteria were randomly divided into two groups: 3% NAC and 20% zinc oxide. Topical product was used after each diaper change. Mothers were taught non-pharmacological measures such as washing after each diaper change so that the two groups were not different in terms of non-pharmacological measures. Patients' information including age, sex, weight, underlying diseases, and medications were extracted from the file. In addition to the initial assessment (day 1), the severity of the lesions was assessed on days 3 and 5. The patients of the two groups were compared in terms of the duration of the disease and the degree of reduction in the severity of dermatitis. This study is a double-blind clinical trial in which the patient and analysts had no information about the individuals in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion: Patients aged less than 2 years who had been diagnosed with diaper dermatitis. Exclusion: Secondary infectious dermatitis; use of any kind of corticosteroid; a history of atopic dermatitis, candidiasis, or seborrheic dermatitis; birth defect.

Intervention groups

Intervention group: patients receiving topical N-Acetylcysteine. Control group: patients receiving topical Zinc Oxide.

Main outcome variables

The severity of erythema and irritation, the extent of diaper dermatitis, presence or absence of papules and pustules, examination of uncoated surface skin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N6**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **retrospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

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

2019-06-22, 1398/04/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-07-11, 1398/04/20

Actual recruitment end date

2019-11-03, 1398/08/12
Trial completion date
2019-11-03, 1398/08/12

Scientific title
Comparison of the Effectiveness of Topical N-Acetylcysteine and Zinc Oxide in the Treatment of Diaper Dermatitis

Public title
Topical N-Acetylcysteine and Zinc Oxide in the Treatment of Diaper Dermatitis

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
Actual sample size reached: 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 N-acetylcysteine 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 participants, the caregivers, and one of the researchers (Nazgol Kermanshahi) collecting and assessing data were unaware of the assigned intervention.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi university of medical science
Street address
Shahid Sadoughi university of medical science, Shohadai Gomnam Blvd, Professor Hesabi Blvd
City
Yazd
Province
Yazd
Postal code
8915173149

Approval date
2019-05-19, 1398/02/29

Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.083

Health conditions studied

1

Description of health condition studied
Diaper Dermatitis

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 3% N-acetylcysteine 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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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

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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

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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Person responsible for updating data**Contact****Name of organization / entity**

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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