Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash in children less than two years old that referred to Amiralmomenin Hospital in Semnan

Protocol summary

Study aim

Determination of the severity of diaper rash before and after intervention in two groups receiving zinc and chamomile cream

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

Childrens who are under two years old and suffer from diaper rash are smears of KOH for the study of people with fungal dermatitis and are excluded. People who have not immunodeficiency or underlying skin conditions, eczema, congenital disease, diabetes and oral thrush, and not used drugs for treatment. After obtaining the consent and training of mothers about the use of children by using randomized six blocks based on severity of dermatitis, they are randomly divided into two groups.Both groups have one type of disposable diaper and one group is treated with chamomile cream 3% and the other group with zinc oxide cream 25% and each day use it 4 times. And the amount of each cream used to cover the lining is about 1 mm thick and is covered by 1 centimeter around the lesion. Each of the them is evaluated by a checklist who completes the questionnaire. Due to the blindness of the study, the researcher and the mother do not know how to assign the worms to each child. The tools used will be a measure of the severity of diaper dermatitis. This is completed every 48 hours for samples and the corresponding score will be recorded in the form.

Participants/Inclusion and exclusion criteria

Entrance:All children under two years old and more than 2500 grams and more than 37 weeks of gestational age at birth Exit: People with fungal dermatitis, immunodeficiency or underlying skin conditions, eczema, congenital disease, diabetes and oral thrush, who have used drugs to treat lesions.

Intervention groups

A group treated with Zinc oxide cream 25% and the other group will be treated with chamomile cream 3%.

Main outcome variables

Severity of diaper rash

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190330043141N1**
Registration date: **2019-05-21, 1398/02/31**
Registration timing: **prospective**

Last update: **2019-05-21, 1398/02/31**
Update count: **0**

Registration date

2019-05-21, 1398/02/31

Registrant information

Name

Zeinab Pourzahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash in children less than two years old that referred to Amiralmomenin Hospital in Semnan

Public title
Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All children under the age of two years,more than 2500 gram weight and more than 37 weeks of gestational age suffering from diaper rash
Exclusion criteria:
Having severe infectious or fungal infections Having oral candidiasis Use of other medication for treatment Admission to Oncology ward immune deficient
Age
From **1 day** old to **24 months** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with Diaper Dermatitis are divided into blocks of six patients, based on severity of dermatitis, and each block is randomly divided into two groups, one group treated with zinc oxide cream and one group treated with chamomile cream.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each person will be assigned a study in code A and B that only the researcher will know about the division of the groups. The outcome evaluator and the participants will be unaware of the groups. Also, Chamomile and Zinc oxide cream are similar in appearance and color and packaging.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Amir Kabir Blvd,Semnan
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Postal code
3514799442
Approval date
2019-04-25, 1398/02/05
Ethics committee reference number
IR.SEMUMS.REC.1398. 173

Health conditions studied

1

Description of health condition studied
Diaper rash
ICD-10 code
L22
ICD-10 code description
Diaper [napkin] dermatitis

Primary outcomes

1

Description
severity of diaper rash
Timepoint
Day one, third, fifth treatment
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chamomile Cream 3%, prepared by the pharmacist from the Chamomile extract for five days, is used daily 4 times as large as about 1 mm on the lesion
Category
Treatment - Drugs

2

Description
Intervention group: zinc oxide cream producted by Minoo for five days, is used daily 3 times as large as about 1 mm on the lesion
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Pantea Tajik
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology of Semnan 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
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Position
Pediatric resident
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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