Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the Effectiveness of topical application of zinc oxide 25% versus zinc oxide 25% plus breastmilk on children under 1 year old with diaper dermatitis ; a randomised controlled trial

Protocol summary

Study aim

Comparison of the effect of breast milk combined with zinc oxide and zinc oxide alone in the treatment of diaper dermatitis

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 42 patients.

Settings and conduct

After taking the code of ethics, 42 of the infants under one year referred to Bahrami Children's Hospital will be selected after applying the inclusion and exclusion criteria. Random numbers are assigned in a 1:1 ratio to two groups of 21 people A and B. The researchers will record the characteristics in a checklist and will perform an initial evaluation of the diaper dermatitis of the infants participating in the study using the Buckley scale. They receive a score from 0 to 6; a score of 0 indicates the lowest and a score of 6 indicates the highest level of involvement. The first group will be treated with local breast milk every 12 hours along with 25% zinc oxide from Caspian Pharmaceutical Company, every 12 hours, and the second group will be treated only with 25% zinc oxide from Caspian Pharmaceutical Company, every 12 hours. The treatment method adopted in each person will continue for 7 days and the parents/guardian of the child will be asked not to use any other topical medicine during the study. Finally, the recovery process of people in two groups will be compared and evaluated based on other demographic variables and the use of the Buckley scale.

Participants/Inclusion and exclusion criteria

Infants under one year who do not have underlying systemic disease and have not received local treatment before.

Intervention groups

In this study, 42 infants under one year will be divided into two equal groups. The control group will be treated with breast milk and topical zinc oxide. The control group will be treated with topical zinc oxide alone.

Main outcome variables

The severity of the injury, recovery period, complete recovery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220630055329N1**
Registration date: **2023-04-19, 1402/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-19, 1402/01/30**
Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Pardis Aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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aghaeipardis@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-11-22, 1402/09/01

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

Scientific title
Comparison of the Effectiveness of topical application of zinc oxide 25% versus zinc oxide 25% plus breastmilk on children under 1 year old with diaper dermatitis ; a randomised controlled trial

Public title
Effectiveness of topical application of zinc oxide 25% versus zinc oxide 25% plus breastmilk on diaper dermatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infants under 1
Exclusion criteria:
previous topical treatments systemic conditions
Age
To **1 year** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to control variables, stratified randomization method will be used. To create a random sequence, age above and below six months and the type of milk as consumption or non-consumption of supplemental milk are considered, and thus four lists include 1- children under six months who drink supplemental milk, 2- children under six months who don't drink supplemental milk, 3- those over 6 months old who drink supplemental milk and 4- those over 6 months old who do not drink supplemental milk will be considered. Then, using random numbers software to determine the order of treatment (topical valve+ zinc oxide and zinc oxide alone) from 2 blocks A and B (instead of each of the treatments and in the form of A B and B) will be used. The study groups are: Group One: Topical Milk+ Zinc Oxide and Group Two: Zinc Oxide alone. Also, randomization tools, random sequence software (Random Allocation Software, Version 2.0) will be accessible from the address. https://random-allocation-software.informer.com/2.0
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is one blind, in which the researcher and analyzer of the data will be blind and the patient will not be blind. For this purpose, the type of treatment will be given to the interface based on the blocks made in the sealed envelopes. In order to hide random allocation, non -loose -end envelopes will be used with random sequences. Each of the random sequences created is recorded on a card and the cards are placed in the envelope of the letter respectively. In order to maintain random sequences, the outer surface of the envelopes is done in the same way. Finally, the envelopes will be sealed and placed in a box respectively. At the beginning of the registration of participants, one of the envelopes is opened by the trained person, and the assigned group of the participant is determined. The patient will be aware of the type of treatment, but the researcher and the analyzer will be blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran university of medical sciences
Street address
Ethics committiee , first floor , faculty of medicine , building no.1 , northern door , poorsina st. , ghods st. , enghelab st.
City
Tehran
Province
Tehran
Postal code
١٤٦٥٧٧٧٨٤١
Approval date
2022-08-31, 1401/06/09
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.402

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
Zinc oxide application
Timepoint
Before intervention, one week after intervention
Method of measurement
Buckley scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after determining the type of treatment, how to use breast milk or zinc will be explained to the child's caregiver in a ten-minute session by a trained mediator, and learning it (through an oral test) It will be ensured by the caregiver and an educational video will be sent to him. Due to the sensitive age of the participants in the study and the annoying and painful nature of this disease, and the uncertainty of breast milk treatment for diaper dermatitis, an approved treatment (25% zinc oxide) will be used in the intervention group besides breast milk, and the intervention group will be treated with local breast milk every 12 hours along with 25% zinc oxide from Caspian Pharmaceutical Company, every 12 hours. Caspian's zinc oxide contains 25 grams of zinc oxide per 100 grams, and during the treatment, approximately two tubes of it will be used for 14 times overally .It will also be recommended that the breast milk consumed be freshly expressed and not exposed to cold or other pollutants, and be applied on the baby's skin with a sterile applicator prepared by the research team, and about 3 cc of breast milk will be enough for each use (14 times in total). The treatment method adopted in Each person will continue for 7 days and in the entire affected area, and the child's parents/guardian will be asked not to use any other topical medicine during the study, and also wash the child only with warm water after each urination or defecation, dry it with air flow and change his diaper, and at the appointed time, use breast milk or ointment , and after it dries, diaper the child. In the future, the condition of the disease will be evaluated in each patient on a daily basis through available photo sending softwares, and any improvement or aggravation of the lesions will be recorded.
Category
Treatment - Drugs

2

Description
Control group: In this study, we compare the effect of breast milk combined with zinc oxide, against the use of zinc oxide alone. After determining the type of treatment, the method of using zinc will be explained to the child's caregiver practically in a ten-minute session by a trained mediator, and its learning (through an oral test) will be ensured by the caregiver. An educational video will also be sent to him. Patients in the control group will be treated with zinc oxide 25% by Caspin Pharmaceutical Company, every 12 hours. Zinc oxide by Caspin Company contains 25 grams of zinc oxide per 100 grams and during the treatment (for a total of 14 uses) approximately Two tubes will be used. The treatment method adopted in each person will continue for 7 days and in the entire area involved in diaper rash, and the parents/guardian of the child will be asked not to use any other topical medicine during the study, and also Wash the child with warm water after each urination or defecation (and before each drug application) ,let it dry with air flow and change his diaper and use breast milk or ointment before putting on diapers at the appointed time. The condition of the disease will be evaluated on a daily basis through available photo sending Apps and any recovery or aggravation of the lesion will be recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami hospital
Full name of responsible person
Dr alireza shafiee esfidvajani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr alireza shafiee esfidvajani
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
Medical doctor
Other areas of specialty/work
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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