

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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)

Phone

+98 21 3660 8312

Email address

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

۱۷۶۰۷۷۷۸۶۰

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 overallly .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

Street address

Damavand st kiaee st bahrami children's hospital

City

Tehran

Province

Tehran

Postal code

۱۷۶۷۷۷۸۶۰

Phone

+98 21 3660 8312

Email

Aghaeipardis@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

tehran university of medical sciences, research department

Street address

Damavand st kiaee st bahrami hospital

City

Tehran

Province

Tehran

Postal code

۱۷۶۰۷۷۷۸۶۰

Phone

+98 21 3660 8312

Email

Aghaeipardis@yahoo.com

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

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Damavand st kiaee st bahrami hospital

City

Tehran

Province

Tehran

Postal code

1765777865

Phone

+98 21 3660 8312

Email

Aghaeipardis@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Alireza shafiee esfidvajani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Damavand st

City

Tehran

Province

Tehran

Postal code

۱۷۶۰۷۷۷۸۶۰

Phone

+98 21 3660 8312

Email

Aghaeipardis@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Pardis aghaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Damavand st

City

Tehran

Province

Tehran

Postal code

۱۷۶۰۷۷۷۸۶۰

Phone

+98 21 3660 8312

Email

Aghaeipardis@yahoo.com

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