Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Caring Program in Prevention of Diaper Dermatitis in Hospitalized Infants: Randomized Clinical Trial

Protocol summary

Study aim
Determining and Comparing the Incidence,, extent and severity of diaper dermatitis in two control and intervention groups at different times of evaluation.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 90 patients, random assignment through land list software

Settings and conduct
In this study, infants will enter the study from the first day of hospitalization. The care program will be practically taught by the executive researcher to the mothers of the intervention group to implement this care program for their baby from the first day of hospitalization at least for 5 days. The care program is designed based on experimental texts, systematic review studies and trials. Each part is taught by the researcher to the mothers. Routine care will be performed for the control group. In the routine program of mothers, each time after defecation, the baby wipes the diaper area with a cotton ball soaked in water and, if necessary, the baby is washed. The outcomes of the study and data analysis will be performed by a researcher who is unaware that the infant is assigned to study groups.

Participants/Inclusion and exclusion criteria
inclusion; The infant is less than 28 days old; The infant weighs between Baby 2500 mg to 4 kg ; Feed the infant with breast milk; The infant's mother presence bed side. exclusion; The infant has congenital diabetes; The infant has a congenital skin disease; The infant should receive immunosuppressive drugs.

Intervention groups
Intervention group; The care program will be practically trained by the executive researcher to the mothers of the intervention group. Control group; In this group, according to the routine program of the mothers, each time after defecation, the diaper area is wiped with cotton soaked in water.

Main outcome variables
The incidence; Extent; Severity of dermatitis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100823004617N16**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date
2021-01-03, 1399/10/14

Registrant information

Name
Mahnaz Jabraeili

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-01, 1399/10/12

Expected recruitment end date
2021-04-01, 1400/01/12

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Caring Program in Prevention of Diaper Dermatitis in Hospitalized Infants: Randomized Clinical Trial

Public title

The Effect of Caring Program in Prevention of Diaper Dermatitis in Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The infant is less than 28 days old. The infant weighs between 2.5 and 4 kg. Feed the infant with breast milk. The infant's mother should be by his side constantly.

Exclusion criteria:

If the infant has diaper dermatitis at the beginning of the study. The infant has congenital diabetes. If the mother does not want to continue studying. The infant has a congenital skin disease. The infant should receive immunosuppressive drugs. Infants admitted with a diagnosis of sepsis. The infant has known known drug and food allergies. The mother of the infant should not follow the care plan.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Rand List software, through blocks of 4 and 6, they will be randomly divided into two groups of intervention and control (control group = A and intervention group = B). The random sequence created will be covered using allocation envelopes (Allocation concealment) and the envelopes will be given to the executive nurse in order of number. After opening the envelope, the type of baby group will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome of the study, Incidence, severity and extent dermatitis, which will be measured daily with the help of a researcher who is not aware of the infant being assigned to study groups., and so, The data analyzer will not know how to assign groups to study groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

School of Nursing and Midwifery., Shariati Sreeet., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.TBZMED.REC.1399.818

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

"Percentage of infants with dermatitis"

Timepoint

"The effect of care program on dermatitis prevention" Measuring the incidence, extent and severity of dermatitis up to 5 days after the intervention

Method of measurement

"Assess infant skin through observation"

2

Description

"Measuring the extent of diaper dermatitis"

Timepoint

"Daily for 5 days"

Method of measurement

"Using dermatitis extent scale designed by Dabirian (1999)"

3

Description
"Measuring the severity of diaper dermatitis"
Timepoint
"Daily for 5 days"
Method of measurement
"Measurement of dermatitis severity using the 2005 Al Waili five-point scale"

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: In the intervention group, the caring plan will be taught theoretically and practically (face to face) to mothers by the researcher in a one-hour session in the infant's bedside. This plan will be implemented in five parts. First, basic training on skin care is given, then how to use diaper, including when and how to change it. In the third part, instructions on how to clean the diaper area and in the fourth part, the use of protective creams are presented, at the end, the symptoms of dermatitis and related care will be taught. From the first day of hospitalization until discharge (for at least 5 days), the mother will do this caring plan, and the researcher will monitor how it is implemented and provide corrective feedback to the mother if needed. The educational items will be provided to mothers in the form of a pamphlet.
Category
Prevention

2

Description
Control group: In this group, routine care will be performed. In the routine care, the mothers learns how to clean the diaper area. In this training, mothers are advised to clean the diaper area with water-soaked cotton after each defecation and use zinc oxide ointment if the skin becomes red. After completing the study, an educational pamphlet will be provided to the mothers of the control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Mahnaz Jabraeili
Street address
School of Nursing and Midwifery., Shariati Street., Tabriz.
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5138947
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jabraeilim@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei
Street address
No. 2 Central Building, Research Deputy of Tabriz University of Medical Sciences., Golgasht Street., Tabriz,
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5165665931
Phone
+98 41 3334 4280
Email
research-vice @tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahnaz Jabraeili
Position
Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available