Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation effect of topical application of magnesium 2% , althaea officinalis 5% and althea officinalis 5% plus magnesium 2% Cream containing compare with calendula cream in the treatment of Diaper Dermatitis in Children.

Protocol summary

Summary

The aim of this study was the effect of topical application of magnesium 2% , althaea officinalis 5% and althea officinalis 5% plus magnesium 2% Cream containing compare with calendula cream in the treatment of Diaper Dermatitis in Children referred to Pediatric and neonatal ward in Hajar Hospital of Shahrekord. This study is a double blind clinical trial, placebo-controlled, single-center is 128 children referred to pediatric who fulfilled inclusion criteria: diagnosis of diaper rash; children under two years. Exclusion criteria: other diseases such as lupus divided into 4 groups of 32, first group used althaea officinalis 5% cream containing and the second group cream containing magnesium 2% and the third group combines althaea officinalis5% and magnesium 2%and the fourth group receive Calendula Cream, 3 times a day after changing diaper in place. Follow-up treatment is performed on days 3 and 7.Patients with improved diaper rash symptoms are considered to be responding to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041710222N6**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

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keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of topical application of magnesium 2% , althaea officinalis 5% and althea officinalis 5% plus magnesium 2% Cream containing compare with calendula cream in the treatment of Diaper Dermatitis in Children.

Public title

Effect of topical application of magnesium 2% , althaea officinalis 5% and althea officinalis 5% plus magnesium 2% Cream containing compare with calendula cream in the treatment of Diaper Dermatitis in Children.

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of diaper rash; children under 2 years. Exclusion Criteria: other diseases with diaper rash such as lupus.
Age
To **2 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrekord University of Medical Sciences
Street address
Kashani street, shahrekord university of medical sciences, shahrekord
City
Shahrekord
Postal code
Approval date
2016-01-17, 1394/10/27
Ethics committee reference number
IR.SKUMS.REC.1394.93

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
diaper rash symptom
Timepoint
Baseline and two weeks later
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
, first group used althaea officinalis 5% cream containing and the second group cream containing magnesium 2% and the third group combines althaea officinalis5% and magnesium 2% Cream 3 times a day after changing diaper topical use in place.
Category
Treatment - Drugs

2

Description
the control group used receive Calendula Cream 3 times a day after changing diaper topical use in place
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital
Full name of responsible person
Abolfazl Khoshde
Street address
Hajar Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahrekord University of Medical Scie
Full name of responsible person
Dr. Kamal Solati
Street address

Shahrekord University of Medical Sciences, Kashani street, Shahrekord

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of Medical Scie

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Abolfazl Khoshdel

Position

Pediatrician, Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty