

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effect of topical application Chamomile and Calendula on the recovery rate of diaper dermatitis

Protocol summary

Summary

The objective of the present randomized control clinical and double-blind trial is to compare the effect of topical application chamomile and calendula on the recovery rate of diaper dermatitis. 90 infants (aged 6 through 12 month) with diaper dermatitis randomized to receive topical calendula ointment (n=45) or chamomile ointment (n=45). Children in each group were treated with the respective topical three times a day for a period of 3 days. Parents were instructed to wash diaper area with lukewarm water during diaper change and—after drying—treat the area only with the administered medication. The severity and extent of dermatitis was graded at baseline as well as days 3 and 7 of study using a 5-point scale (from 0 to 4). Then recovery of diaper dermatitis will calculate and compare in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302284617N4**

Registration date: **2013-04-07, 1392/01/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-07, 1392/01/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Council of Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-10, 1392/02/20

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of topical application Chamomile and Calendula on the recovery rate of diaper dermatitis

Public title

Comparison the effect of topical application Chamomile and Calendula on diaper dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infants aged among 6-12 months; patients who had not secondary infections and treated with corticosteroids or had not sensitivity to any of the study medications. Exclusion criteria: there is known diseases that require to special treatment; using other drugs for healing diaper dermatitis; using antibiotics during research and there is fungal dermatitis by exploration of physician.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Deputy of research, Tabriz University of Medical Sciences

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977-5138947

Approval date

2013-02-16, 1391/11/28

Ethics committee reference number

5/4/10785

Health conditions studied**1****Description of health condition studied**

Diaper rash

ICD-10 code

I 22

ICD-10 code description

Diaper [napkin] dermatitis

Primary outcomes**1****Description**

Severity of dermatitis

Timepoint

Baseline, days 5 and 10 of study

Method of measurement

5-point scale for severity of diaper dermatitis

Secondary outcomes**1****Description**

Dermatitis Extent- sid effect

Timepoint

Baseline, days 5 and 10 of study

Method of measurement

Checklist

Intervention groups**1****Description**

Control group: In the control group, is used 1.5% Calendula. Parents were instructed to wash diaper area with lukewarm water during diaper change and—after drying—treat the area only with the administered medication that they were not informed of the type. The severity and Extent of dermatitis was graded at baseline as well as days 3 and 7 of study.

Category

Treatment - Drugs

2**Description**

In the Intervention group, is used 3% chamomile; parents were instructed to wash diaper area with lukewarm water during diaper change and—after drying—treat the area only with the administered medication that they were not informed of the type. The severity and Extent of dermatitis was graded at baseline as well as days 3 and 7 of study.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ardabil Social Security Hospital

Full name of responsible person

Zahra Afshari

Street address**City**

Ardabil

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Council of Tabriz University of Medical

Sciences

Full name of responsible person

Dr. Ostad Rahimi

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Research Council of Tabriz University of Medical Sciences, Golgasht street , Tabriz

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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

Research Council of Tabriz University of Medical Sciences

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

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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