Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Chamomile and Calendula ointment on controlling the severity of diaper dermatitis in NICU (Neonatal, Intensive Care Unit).

Protocol summary

Study aim
Comparison of the effect of Chamomile and Calendula ointment on controlling the severity of diaper dermatitis in NICU.

Design
The clinical trial with two groups (intervention and control) with a sample size of 80 individuals, pragmatic, double-blind, randomized

Settings and conduct
This study was conducted to compare the effect of chamomile ointment and calendula ointment on controlling the severity of diaper dermatitis in NICU newborns in Hashamateyeh Hospital in Sabzevar city. The outcome evaluator and the participants will be unaware of how the grouping is organized. Patients were randomly assigned to the first intervention group (Chamomile ointment) and second intervention group (Calendula ointment). The response to treatment is evaluated a 5-point scale at the end of day 5 after intervention for both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mild to moderate diaper dermatitis with score one and two (limited to perineal and hips). Exclusion Criteria: Having a defective immune system, Get Immunosuppressive Drugs, Sepsis, Oral thrush (Candidiasis), eczema, congenital diseases, fungal dermatitis, Having urinary tract infection (UTI) and skin allergy.

Intervention groups
First intervention group: Patients in this group use Chamomile ointment, each containing 100 grams of an ointment containing 45 grams of chamomile essential oil, topically 3 times a day for 5 days. Second intervention group: Patients in this group use Calendula ointment, each containing 100 grams of an ointment containing 35 mg of extract of the plant, topically 3 times a day for 5 days.

Main outcome variables
Determine the severity of diaper dermatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N10**
Registration date: **2019-02-02, 1397/11/13**
Registration timing: **prospective**

Last update: **2019-02-02, 1397/11/13**
Update count: **0**

Registration date
2019-02-02, 1397/11/13

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4401 8337

Email address
sahebkarm@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-05, 1397/11/16

Expected recruitment end date
2019-04-05, 1398/01/16

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Chamomile and Calendula ointment on controlling the severity of diaper dermatitis in NICU (Neonatal, Intensive Care Unit).

Public title

Comparison of the effect of Chamomile and Calendula ointment on controlling the severity of diaper dermatitis in NICU.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate diaper dermatitis with score one and two (limited to perineal and hips).

Exclusion criteria:

Having a defective immune system Get Immunosuppressive Drugs Sepsis, oral thrush (Candidiasis), eczema and congenital diseases and fungal dermatitis Having urinary tract infection (UTI) and skin allergy

Age

From **1 month** old to **12 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted based on a permutation block, Accordingly, 20 blocks were allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B were treated with Chamomile ointment and Calendula cream, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person will be assigned a study code A and B, which will only be known to the researcher of the type of groups. The outcome evaluator and the patients are unaware of the groups. It should be noted that chamomile ointment oil and Calendula cream have been similar in appearance, color, and packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.MEDSAB.REC.1397.089

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

Determine the severity of diaper dermatitis

Timepoint

At the beginning of the study (before the intervention), 3 and 5 days after the intervention

Method of measurement

Determination of the severity of dermatitis based on 5-point scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group use chamomile ointment, each containing 100 grams of an ointment containing 45 grams of chamomile essential oil, topically

3 times a day for 5 days.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group use Calendula ointment, each containing 100 grams of an ointment containing 35 mg of extract of the plant, topically 3 times a day for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatiyeh hospital

Full name of responsible person

Mahbube Navidi

Street address

Heshamatiyeh Hospital, Asadabady Ave., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1014

Email

mahbube.navidi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8319

Email

Drghorat@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Hassan Salehipoor

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8337

Email

Salehipoor45@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Hassan Salehipoor

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province
Razavi Khorasan
Postal code
9671965751
Phone
+98 51 4401 8337
Email
Salehipoor45@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mahbube Navidi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8337
Email
mahbube.navidi@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
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available