

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash in children less than two years old that referred to Amiralmomenin Hospital in Semnan

#### Protocol summary

##### Study aim

Determination of the severity of diaper rash before and after intervention in two groups receiving zinc and chamomile cream

##### Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

##### Settings and conduct

Childrens who are under two years old and suffer from diaper rash are smears of KOH for the study of people with fungal dermatitis and are excluded. People who have not immunodeficiency or underlying skin conditions, eczema, congenital disease, diabetes and oral thrush, and not used drugs for treatment. After obtaining the consent and training of mothers about the use of children by using randomized six blocks based on severity of dermatitis, they are randomly divided into two groups. Both groups have one type of disposable diaper and one group is treated with chamomile cream 3% and the other group with zinc oxide cream 25% and each day use it 4 times. And the amount of each cream used to cover the lining is about 1 mm thick and is covered by 1 centimeter around the lesion. Each of the them is evaluated by a checklist who completes the questionnaire. Due to the blindness of the study, the researcher and the mother do not know how to assign the worms to each child. The tools used will be a measure of the severity of diaper dermatitis. This is completed every 48 hours for samples and the corresponding score will be recorded in the form.

##### Participants/Inclusion and exclusion criteria

Entrance: All children under two years old and more than 2500 grams and more than 37 weeks of gestational age at birth  
Exit: People with fungal dermatitis, immunodeficiency or underlying skin conditions, eczema, congenital disease, diabetes and oral thrush, who have used drugs to treat lesions.

##### Intervention groups

A group treated with Zinc oxide cream 25% and the other group will be treated with chamomile cream 3%.

##### Main outcome variables

Severity of diaper rash

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190330043141N1**

Registration date: **2019-05-21, 1398/02/31**

Registration timing: **prospective**

Last update: **2019-05-21, 1398/02/31**

Update count: **0**

##### Registration date

2019-05-21, 1398/02/31

##### Registrant information

##### Name

Zeinab Pourzahabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3346 3401

##### Email address

zeinab.purzahabi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2019-08-23, 1398/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash in children less than two years old that referred to Amiralmomentin Hospital in Semnan

**Public title**

Comparison of Camomil cream and Zinc Oxide cream in treatment of diaper rash

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All children under the age of two years, more than 2500 gram weight and more than 37 weeks of gestational age suffering from diaper rash

**Exclusion criteria:**

Having severe infectious or fungal infections Having oral candidiasis Use of other medication for treatment Admission to Oncology ward immune deficient

**Age**

From **1 day** old to **24 months** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients with Diaper Dermatitis are divided into blocks of six patients, based on severity of dermatitis, and each block is randomly divided into two groups, one group treated with zinc oxide cream and one group treated with chamomile cream.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Each person will be assigned a study in code A and B that only the researcher will know about the division of the groups. The outcome evaluator and the participants will be unaware of the groups. Also, Chamomile and Zinc oxide cream are similar in appearance and 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 Semnan University of Medical Sciences

**Street address**

Amir Kabir Blvd, Semnan

**City**

semnan

**Province**

Semnan

**Postal code**

3514799442

**Approval date**

2019-04-25, 1398/02/05

**Ethics committee reference number**

IR.SEMUMS.REC.1398. 173

**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**

severity of diaper rash

**Timepoint**

Day one, third, fifth treatment

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

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

Intervention group: Chamomile Cream 3%, prepared by the pharmacist from the Chamomile extract for five days, is used daily 4 times as large as about 1 mm on the lesion

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: zinc oxide cream produced by Minoos for five days, is used daily 3 times as large as about 1 mm on the lesion

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Amiralmomenin hospital

**Full name of responsible person**

Pantea Tajik

**Street address**

Mostafa Khomeini blvd

**City**

semnan

**Province**

Semnan

**Postal code**

3514799442

**Phone**

+98 23 3346 3401

**Email**

pata15000@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Deputy of Research and Technology of Semnan University of Medical Sciences

**Street address**

Amir kabir blvd

**City**

SEM NAN

**Province**

Semnan

**Postal code**

3514799442

**Phone**

+98 23 3344 1022

**Email**

rds@semums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Deputy of Research and Technology of Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Zeinab Pourzahabi

**Position**

Pediatric resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

No 185, Sevome Malek Ave, Malek street, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3519733585

**Phone**

+98 23 3346 0878

**Email**

zeinb.purzahabi@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Pantea Tajik

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Mostafa khomeini blvd, Amiralmomenin hospital, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3514799442

**Phone**

+98 23 3346 3401

**Email**

pata15000@gmail.com

**Fax****Email**

zeinab.purzahabi@gmail.com

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

Semnan University of Medical Sciences

**Full name of responsible person**

Zeinab Pourzahabi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Amiralmomenin hospital, mostafa khomeini Blvd,  
semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3519733585

**Phone**

+98 23 3346 3401

**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