

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Effect of 4% Topical Sucralfate in Erosive Candidial Diaper Dermatitis

Protocol summary

Study aim

Determining the effect of 4% topical sucralfate in the treatment of erosive diaper dermatitis with candidiasis

Design

This study is a double-blind randomized clinical trial study (the patient and the examiner are blinded to the type of treatment) in which outpatients who visited the pediatric dermatology clinic of Imam Hossein (AS) Hospital in Isfahan between July 1401 and July 1402 or have been hospitalized in this center, they will be included in the study randomly in two groups. Written consent will be obtained from the parents of the children before entering the study and after explaining the study method.

Settings and conduct

The medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a completely covering thin layer on the skin. Necessary training will be given to the mother on how to use the medicine during the first visit. The place of study is Imam Hossein Children's Hospital, Isfahan.

Participants/Inclusion and exclusion criteria

Children less than two years and more than 30 days

Intervention groups

Intervention group: The medicine used is 4% sucralfate gel, the medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a thin layer covering the skin.

Main outcome variables

Diaper dermatitis severity percentage before, 3, 7 and 10 days after the intervention in case and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056230N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Seyedh Zahra Moosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4429 9733

Email address

szm.gp68@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 4% Topical Sucralfate in Erosive Candidial Diaper Dermatitis

Public title

Investigation of 4% topical sucralfate in the topical treatment of children with diaper dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children less than 2 years after infancy with a new

clinical diagnosis of Candidiasis Rosacea due to diaper movement

Exclusion criteria:

Age

From **30 days** old to **2 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **4**

First, third, seventh, tenth days

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of School of Medicine - Isfahan
University of Medical Sciences

Street address

Isfahan University of Medical Sciences, No.1, Hezar
jarib Blvd, Isfahan, Islamic Republic of Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-07-31, 1401/05/09

Ethics committee reference number

IR.MUI.MED.REC.1401.179

Health conditions studied

1

Description of health condition studied

Erosive Candidial Diaper Dermatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Diaper dermatitis severity percentage before, 3, 7 and 10 days after the intervention in case and control groups

Timepoint

First, third, seventh and tenth days

Method of measurement

Diaper Severity Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The medicine used is 4% sucralfate gel, the medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a thin layer covering the skin. The drug will be administered in the Faculty of Pharmacy of Isfahan University of Medical Sciences under the supervision of a pharmacist. To prepare one hundred grams of four percent sucralfate gel, first heat 85 ml of purified water on an electric heater until it reaches the boiling temperature, and after turning off the heat source at a temperature of 80 degrees Celsius, add 180 mg of methyl paraben and 20 A milligram of propyl paraben will be added to it, and then at a temperature of 50 degrees Celsius, one gram of carbomer 934, which has already been weighed, will be added to the formula. Half an hour later, that is, when the carbomer was hydrated, the formulation was stirred for 10 minutes with the help of a glass rod, and when the temperature of the formulation reached about 25 degrees Celsius, 4 grams of sucralfate powder, which was previously dissolved in ten milliliters of water, was added. The solution is added to the base and stirred with a glass rod for ten minutes until a homogeneous formulation is obtained. If the pH of the formulation is acidic, two drops of triethanolamine will be added and stirred to neutralize it. Finally, the final formulation will be packed in soft tubes. The contents on the tube box (consumer instructions) include the following: This medicine can only be used for skin use and under the supervision of a physician. In case of any skin reaction, consult the physician. The medicine should be stored at a temperature below 25 degrees Celsius and in a dry and cool place, away from direct sunlight and out of the reach of children. After opening the medicine tube, it can be used for up to one month at room temperature. Do not leave it in the environment and close it tightly. Avoid applying the medicine in sensitive areas such as around the eyes or on the face. Sample Size and Sampling Method: The sample size required for this study was calculated using the sample size

estimation formula to compare the averages mentioned below and considering the confidence level of 95%, the power of the test is 80%, the average number of times for Improvement of lesions in a similar study and taking into account the minimum significant difference between the two groups of case and control for 1 day, the number of samples required in each of the case and control groups was estimated to be 22 people, taking into account 10% sample loss. Eligible people to enter the study are randomly assigned to each of the case and control groups in a random permutation block method with a size of 4. How to use the medicine: The medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a completely covering thin layer on the skin. Necessary training will be given to the mother on how to use the medicine during the first visit. How to teach: The health and preventive measures that will be taught to mothers along with taking medicine are as follows: using linen diapers or washable cotton diapers that are washed and rinsed with soap, changing diapers or diapers regularly. As soon as the infant or child urinates, a complete explanation of the causes of diaper dermatitis including detergents, urine, diarrhea, the infant, the type of feeding and the type of diaper or the age of the infant. The number of training sessions: It is proportional to the visits of patients with their parents. Study grouping: In this study, patients are randomly divided into two groups with equal numbers. Both groups received standard treatment for diaper dermatitis including topical clotrimazole three times a day. In addition to being treated with clotrimazole ointment three times a day (every 8 hours), the treatment group is also treated with topical sucralfate 4% every 4 or 5 hours when the child wakes up 5 times a day.

Category

Treatment - Drugs

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

Imam Hossein Hospital of Isfahan

Full name of responsible person

Parisa Iravani

Street address

Imam Hosein Hospital, No.1, Imam khomaini st,

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

Iravaniparisa@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Asgari

Street address

Hezar jarib, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3060

Email

askari@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Moosavi

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Unit. 1, No.8, Alvan 14 Alley, Ebrahimi St, Marzdaran Blva

City

Tehran

Province

Tehran

Postal code

1461886681

Phone

+98 21 4429 9733

Email

szm.gp68@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Moosavi

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Unit. 1, No.8, Alvan 14 Alley, Ebrahimi St, Marzdaran Blva

City

Tehran

Province

Tehran

Postal code

1463735641

Phone

+98 21 4429 9733

Email

szm.gp68@yahoo.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Moosavi

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Unit. 1, No.8, Alvan 14 Alley, Ebrahimi St, Marzdaran Blva

City

Tehran

Province

Tehran

Postal code

1463735641

Phone

+98 21 4429 9733

Email

szm.gp68@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

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