

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of therapeutic effect of topical semi-solid product containing sucralfate, zinc oxide, aloe Vera gel and peppermint essential oil and zinc oxide ointment in natural base containing Ghee oil and comparison with standard treatment containing zinc oxide in normal base in the process of healing and treatment of diaper rash: a pilot study And parallel

Protocol summary

Study aim

Evaluation of the effectiveness and effect of synergism including semi-solid containing sucralfate, zinc oxide, aloe vera gel and peppermint essential oil and animal oil

Design

Clinical trial with control group, community-based and pragmatic, with parallel group, double-blind, randomized, design of 60 patients.

Settings and conduct

This study was performed on infants and children up to 24 months who suffered from diaper rash and referred to the office of Dr.Seighali located on Sattar Khan Street. zinc oxide, aloe vera gel powder, mint essential oil and the second group examines animal oil. According to similar pilot studies, the study population consists of 60 people, and each of The first and second experimental groups and 20 control groups. Patients participate in the study based on the physician's diagnosis of urinary incontinence and according to the patient's demographic information and parents consent, and are placed in one of the control or experimental groups. A pre-prepared informed consent form will also be provided to patients to become fully acquainted with the study process. The benefits of this study can be applied to children.

Participants/Inclusion and exclusion criteria

Inclusion criteria: doctors diagnosis of diaper rash, age range from birth to 24 months, Written consent and parental cooperation. Exclusion criteria: skin infection - fever- parental lake of cooperation.

Intervention groups

Control group: includes 20 children with age range from birth to 24 months with diaper rash, who are treated for 7 days with our desired drug, which contains sucralfate, zinc, peppermint essential oil and aloe vera gel.

Intervention group: The same as the control group, except that they are treated with a placebo that contains zinc.

Main outcome variables

comparison of the severity of burns, frequency of diaper changes and urination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100119003106N42**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 0037

Email address

hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of topical semi-solid product containing sucralfate, zinc oxide, aloe Vera gel and peppermint essential oil and zinc oxide ointment in natural base containing Ghee oil and comparison with standard treatment containing zinc oxide in normal base in the process of healing and treatment of diaper rash: a pilot study And parallel

Public title

Evaluation of therapeutic effect of topical semi-solid product containing sucralfate, zinc oxide, aloe Vera gel and peppermint essential oil and zinc oxide ointment in natural base containing Ghee oil and comparison with standard treatment containing zinc oxide in normal base in the process of healing and treatment of diaper rash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Doctor's diagnosis of having diaper rash Age between one day to 24 months Parental consent to cooperate and use medication

Exclusion criteria:

Existence of deep ulcers, infection or fungal lesions, need for treatment with other drugs such as corticosteroids and antibiotics. Bloody stools Fever Underlying diseases History of allergies to topical products containing zinc, aloe Vera or products contains essential oil of mint, and cow's milk protein

Age

From **1 day** old to **2 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Zu diesem Zweck werden 60 Umschläge (20 mit der ersten Arzneimittelkarte und 20 mit der zweiten Arzneimittelkarte und 20 mit der Placebokarte)

vorbereitet. Umschläge sind mit Nummern von 1 bis 40 gekennzeichnet. Die Patienten werden nach dem Öffnen des versiegelten Umschlags einer von zwei Medikamenten- bzw. Placebogruppen, Nummer 1 bis 40, zugeordnet.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, physicians, researcher and data collector (student) don't know about who was receiving the placebo and who receiving a placebo. The informed consent was obtained from patients and they were informed that they could leave the trial at any time. The coding of the medicine boxes was done by a third party who was not involved in the study and at the end of the study, decryption took place. All tubes of the drug are the same in terms of design and color, while the cover of the prescribed tubes is coded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Pharmaceutical Sciences Branch

Street address

Islamic Azad University, Pharmaceutical Sciences Branch, Dr. Shariati Ave., Qolhak., Yakhchal St., Yasaman Ave., Tehran Town

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.IAU.TMU.REC.1400.317

Health conditions studied

1

Description of health condition studied

Diaper rash

ICD-10 code

L22

ICD-10 code description

Diaper dermatitis

Primary outcomes

1

Description

Diaper Dermatitis Grading Scale.

Timepoint

The beginning of the study (before the intervention) and the second, fourth, sixth days and after the intervention

Method of measurement

Diaper Dermatitis Grading Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group of patients receiving medicine containing zinc oxide and sucralfate and aloe vera gel and peppermint essential oil (made by Pharm.D. students in pharmaceuticals lab in Azad university) for 7 days after each diaper change.

Category

Treatment - Drugs

2

Description

Intervention group: the second intervention group received animal oil made by researchers of the Faculty of Pharmacy of Tehran Azad University of Medical Sciences for 7 days after each diaper change

Category

Treatment - Drugs

3

Description

Control group: Patients take placebo medicine made by researchers of the Faculty of Pharmacy of Tehran Azad University of Medical Sciences, which contains zinc oxide and the usual base for 7 days after each diaper change.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Fariba Seighali , private clinic

Full name of responsible person

Dr. Fariba Seighali

Street address

No. 29, corner of Sarvanaz Boulevard, Patrice Lumumba St., Sattarkhan St, Tehran.

City

Tehran

Province

Tehran

Postal code

193956466

Phone

+98 21 6656 8652

Email

faribaseighali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

Street address

No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0056

Email

hashemian.f@iaups.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elaheh Shaban

Position

Pharm.D. candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy
Street address
No 99, Yasman Alley, Yakhchal street, Gholhak, Dr.
Shariati street
City
Tehran
Province
Tehran
Postal code
193956466
Phone
+98 21 2264 0051
Email
shabanelahe@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Farshad Hashemian
Position
Pharm.D., BCPS, Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
No 99, Yasman Alley, Yakhchal street, Gholhak, Dr.
Shariati street
City
Tehran
Province
Tehran
Postal code
193956466
Phone
+98 21 2264 0599
Email
hashemian.f@iaups.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Elaheh Shaban
Position
Pharm.D. candidate
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No 99, Yasman Alley, Yakhchal street, Gholhak, Dr.
Shariati street
City
Tehran

Province
Tehran
Postal code
193956466
Phone
+98 21 2264 0051
Email
shabanelahe@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data potentially can be shared after being unidentifiable.

When the data will become available and for how long

Just after the articles publication.

To whom data/document is available

For all investigators.

Under which criteria data/document could be used

The person requesting the data should be a relevant expert in this field - All statistical analyzes performed can be provided - Information can be used by mentioning the name of the research and referencing the site to the research - Requirements: Mentioning the name of the research and codes Relevant research and all the required information as well as the name of the researcher and communication channels in case of receiving the required information.

From where data/document is obtainable

Application can refer to the Department of Clinical Pharmacy, Faculty of pharmacy, Tehran Medical Science, Islamic Azad University, Dr. Hashemian or contact the researcher by sending email to shabanelahe@gmail.com or calling 09210907926.

What processes are involved for a request to access data/document

Application can apply for research information by visiting the department or by contacting the e-mail address and telephone number as well as providing information on academic studies and the purpose of requesting the information. Applicant must commit themselves to mention the source. If the request is sent six months after the publication of research information the researcher will send the data to the requesting party by email within a week.

Comments