Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between combination of copper, zinc and sucralfate with white soft paraffin in the treatment of of fissure of nipple in breast feeding female

Protocol summary

Summary

Fissure of nipples are one of the most common causes of unsuccessfully breast feeding during the first few days after birth. There are many modalities for treatment with different therapeutic effects for sore nipples. The treatment of choice for fissure of nipple is emollient such as White soft paraffin. This is a double-blind randomized clinical trial to compare the effect of Cicalfate cream versus White soft paraffin in the treatment of fissure in Beheshti hospital in Kashan. Breast feeding females with fissure of nipple without underlying disease such as Diabetes Mellitus; Rhumathologic Diseases; Malignancy; Abscess and infection in breast will be rnrolled. One hundred patients are enrolled in two groups (Cicalfate cream, and White soft paraffin, randomly. Cicalfate users will be applied Cicalfate cream twice daily on fissure of nipples for 14 days and white soft Paraffin will be applied as the same way. They will be followed at 7th and 14th days after beginning the treatment to monitor the grading and healing of fissure and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901283734N1**
Registration date: **2011-07-26, 1390/05/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-26, 1390/05/04

Registrant information

Name

Rezvan Talaee

Name of organization / entity

Kashan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1445 5370

Email address

talaei-re@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor of research, Kashan University of Medical Sciences

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2013-06-30, 1392/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between combination of copper, zinc and sucralfate with white soft paraffin in the treatment of of fissure of nipple in breast feeding female

Public title

Comparison between combination of copper, zinc and sucralfate with white soft paraffin in the treatment of fissure of nipple in breast feeding female

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :Breast feeding females with fissure of nipple exclusion criteria : underlying disease such as

Diabetes Mellitus; Rhumathologic Diseases; Malignancy; Abscess and infection in breast

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
5th Km of Ghotbe Ravandi Bulv.

City
Kashan

Postal code
8715988141

Approval date
2010-02-24, 1388/12/05

Ethics committee reference number
8852

Health conditions studied

1

Description of health condition studied
fissure of nipple

ICD-10 code
N64.0

ICD-10 code description
Fissure and fistula of nipple

Primary outcomes

1

Description
wound healing

Timepoint
7 and 14 days after intervention

Method of measurement
clinical and physical examination

Secondary outcomes

1

Description
side effects

Timepoint
7 and 14 days after intervention

Method of measurement
clinical examination and interview with patients

Intervention groups

1

Description
Intervention: cicalfate cream (composed of copper, zinc and sucralfate) twice daily for 14 days

Category
Treatment - Drugs

2

Description
Control group: white soft paraffin twice daily for 14 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashan Shahid Beheshti Hospital

Full name of responsible person
Dr. Rezvan Talaee

Street address
Ghotb Ravandi Bulvard

City
Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chanceller of Research, Kashan University of Medical Sciences

Full name of responsible person
Dr. Gholam Ali Hamidi

Street address

Vice Chanceller of Research, Kashan University of Medical Sciences, 5th Kilometer Ghotbe Ravandi Bulv.

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chanceller of Research, Kashan 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

Name of organization / entity

Kashan university of medical sciences

Full name of responsible person

Rezvan Talaee

Position

Dermatologist/ Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Web page address

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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