

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 enrrolled. 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 Talaei

##### 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 Talaei

**Street address**

Ghotb Ravandi Bulvard

**City**

Kashan

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

Vice Chancellor of Research, Kashan University of  
Medical Sciences

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

Vice Chancellor 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 Chancellor 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**

**Street address**

Beheshti Hospital, 5th kilometer of Ghotb ravandi Bul.

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## Person responsible for scientific inquiries

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Dermatologist

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## Person responsible for updating data

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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*