

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety and clinical efficacy of Firooz brand name fissure cream containing lanolin in improving the pain and severity of fissure lesions in lactating women

Protocol summary

Study aim

Evaluation of safety and clinical efficacy of Firooz brand name fissure cream containing lanolin in improving the pain and severity of fissure lesions in lactating women

Design

Single group, before -after, phase 2 clinical study.
sample size is 20. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy in Tehran, 20 lactating women suffering from fissure of nipple will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use Firooz brand lanolin cream on the nipple and areola at least 5 times a day after each breastfeeding. Before intervention and 48 hours and 7 days after that satisfaction of participants will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lactating women aged 18 to 45 with term babies (weighing 2500 to 4000 grams) Chest pain from severity 1 to 3, General health, Signing the consent form for participation in the study
Exclusion criteria: People with puerperal fever, A newborn suffering from jaw and mouth abnormalities such as short frenulum or oral infections, Mothers suffering from diabetes, Use of any local treatment for fissure three days before the study

Intervention groups

Using Firooz brand lanolin cream on the nipple and areola at least 5 times a day after each breastfeeding.

Main outcome variables

Pain during breastfeeding; Severity of fissure of nipple

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N27**

Registration date: **2022-10-29, 1401/08/07**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and clinical efficacy of Firooz brand name fissure cream containing lanolin in improving the

pain and severity of fissure lesions in lactating women

Public title

Evaluation of Firooz fissure cream containing lanolin in improving the pain and severity of fissure lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Lactating women aged 18 to 45 with term babies (weighing 2500 to 4000 grams) General health Signing the consent form for participation in the study Breast pain from severity 1 to 3

Exclusion criteria:

People with puerperal fever A newborn suffering from jaw and mouth abnormalities such as short frenulum or oral infections Mothers suffering from diabetes Use of any local treatment for fissure three days before the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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 committee in research of medical school-
Tehran University of Medical Sciences

Street address

Research and Technology Dept, 6th floor, Central
Organization of the University, Ghods St., Keshavarz
Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.533

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

Pain during breastfeeding

Timepoint

Before intervention, 48 hours and 7 days after that

Method of measurement

By a 6-point Likert scale (Not satisfied at all = 0, Very little = 1, Little = 2, Average = 3, Much = 4 and Very much = 5)

Secondary outcomes

1

Description

Severity of fissure of nipple

Timepoint

Before intervention, 48 hours and 7 days after that

Method of measurement

Severity of fissure of nipple 1 to 3 based on: 0) No microscopically visible skin changes, 1) Erythema or edema or combination of both, 2) Superficial damage with or without scab formation on <25% of the nipple surface, 3) Superficial damage with or without scab formation on >25% of the nipple surface, 4) Partial-thickness wound with or without scab formation on <25% of the nipple surface, 5) Partial-thickness wound with or without scab formation on >25% of the nipple surface

Intervention groups

1

Description

Intervention group: Using Firooz brand lanolin cream on the nipple and areola at least 5 times a day after each breastfeeding.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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1416613675

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+98 21 8897 0658

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Firooz Health Group Company

Full name of responsible person

Seyed Mohamad Mousavi

Street address

Hekmat 8, Sina BLDV.

City

Alborz Industrial City

Province

Qazvin

Postal code

1451614644

Phone

+98 28 3222 3514

Email

e.arastoo@firooz.com

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

Yes

Title of funding source

Firooz Health Group Company

Proportion provided by this source

100

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**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manager of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mansour Nassiri Kashani

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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mnassirik@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable