

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of breast milk and lanolin on sore nipple

Protocol summary

Summary

Sore nipples are one of the most common causes of unsuccessfully breast feeding during the first few days. There are many treatments with different therapeutic effects for sore nipples. The local wage of breast milk for sore nipple treatment is used in many cultures. This is a randomized clinical trial to compare the effect of rubbing breast milk versus lanolin in the treatment of sore nipples in NICU of Emamreza hospital. We randomly divide the patients into 3 groups (breast milk, lanolin, and control). They are visited at third, fifth, seventh and 10th days to monitor the improvement and wound healing and drug side effects. In the first group at end of the each breast feeding, the hind milk is rubbed into the nipple and during the breast will dressed. Lanolin users rubb lanolin into their nipples 3 times a day. The control group is just observed. Then data will analyzed by using spss.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711061162N11**

Registration date: **2009-06-07, 1388/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-06-07, 1388/03/17

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 1121

Email address

mohamadzadeha@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of medical sciences

Expected recruitment start date

2004-07-15, 1383/04/25

Expected recruitment end date

2006-07-15, 1385/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of breast milk and lanolin on sore nipple

Public title

The effect of breast milk and lanolin on sore nipple

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All mothers who their neonates are admitted in NICU of Emamreza hospital and have nipple sore and give milk to baby by breast milk. Exclusion criteria: Abscess and infection in breast that is contraindicated for breast feeding.

Age

From **17 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 225

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research of Mashhad University of medical sciences

Street address

Ghoreshi building, Daneshgah street

City

Mashhad

Postal code

13131-91379

Approval date

2004-07-07, 1383/04/17

Ethics committee reference number

5/1813

Health conditions studied

1

Description of health condition studied

sore nipple

ICD-10 code

N64.0

ICD-10 code description

Fissure and fistula of nipple

Primary outcomes

1

Description

Improving of wound healing.

Timepoint

third, fifth, seventh and tenth days

Method of measurement

Clinical and physical examination

Secondary outcomes

1

Description

side effect

Timepoint

daily

Method of measurement

Clinical examination and interview with mothers

Intervention groups

1

Description

Breast milk group: Rubbing of mother milk on sore nipple

Category

Treatment - Other

2

Description

control group: no intervention

Category

N/A

3

Description

lanolin group: Rubbing of lanolin on sore nipple

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Emamreza hospital

Full name of responsible person

Dr.Ashraf mohammadzadeh

Street address

Neonatal research center- NICU- Emamreza hospital- mashhad-Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of medical sciences

Full name of responsible person

Dr jalil tavakol afshari

Street address

Ghoreshi bulding-daneshgah street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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**

Neonatal Research Center

Full name of responsible person

Dr. Ashraf mohammadzadeh

Position

Neonatologist, professor

Other areas of specialty/work**Street address**

NRC-NICU-Emamreza hospital

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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