

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of Lanolin, Peppermint and Dspanthenol on treatment of traumatic nipple in lactating mothers: a randomized double-blind controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is comparing the effect of Lanolin, Peppermint and Dexpanthenol on treatment of traumatic nipples in lactating mothers. In this study, 126 lactating women aged 18 to 40 years affected by traumatic nipples will be recruited. This study will be conducted at selected health care centers in Sanandaj city. Eligible women will be selected through convenience sampling and will be randomly assigned into 3 groups of 42 persons using permuted block randomization with allocation ratio of 1:1:1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 126, which contains one tube (tubes containing a cream Lanolin, Peppermint and Dexpanthenol , which is similar in shape, color and size) will be used for allocation concealment. Medication immediately after breastfeeding 3 times a day for 2 weeks, some of the drug so that a thin layer of cover around the nipple and areola is applied. Main outcome include nipple trauma injury with Champion scale and secondary outcome include nipple pain with Pain Sttor scale will be assessed by researcher before the intervention and two weeks after the intervention. The researcher and the participants will be blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403116709N16**

Registration date: **2014-10-06, 1393/07/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-06, 1393/07/14

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sciences.

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Lanolin, Peppermint and Dspanthenol on treatment of traumatic nipple in lactating mothers: a randomized double-blind controlled trial

Public title

The effect of Lanolin, Peppermint and Dexpanthenol on

traumatic nipple in lactating mothers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: single birth; exclusive breastfeeding; term infant; infants less than 2 months of age; earn a minimum score 1 on a scale of NTS and NSRS; mother's lack of sensitivity to Lanolin, Peppermint and Dexpanthenol; 2500-4000 grams birth weight; the absence of abnormal nipple (flat, depressed). Exclusion criteria: infant with tongue and teeth abnormalities; baby use pacifier, glass and plastic nipple; mother with history of mental illness

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Postal code

51665-118

Approval date

2014-06-23, 1393/04/02

Ethics committee reference number

9342

Health conditions studied

1

Description of health condition studied

Cracked nipple

ICD-10 code

N64.0

ICD-10 code description

Other disorder of breast

Primary outcomes

1

Description

Nipple trauma injury

Timepoint

Before the intervention and two weeks after intervention

Method of measurement

Champion scale

Secondary outcomes

1

Description

Nipple pain

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

pain Sttor scale

Intervention groups

1

Description

Control group: Lanolin cream with trade name of Lanolin made by Iran Nazhoo Company, containing purest Lanolin and no preservative and any other additives that for 2 weeks 3 times a day immediately after milking, the amount of the drug so that a thin layer of it covers the nipple and areola will be applied.

Category

Treatment - Drugs

2

Description

Intervention group 1: Peppermint cream, made by pharmacy faculty in Tabriz, containing Carbopol, Methyl paraben, Tritanolamin and Glycerin with 0.2% Peppermint oil added to it that for 2 weeks, 3 times a day immediately after milking, the amount of the drug so that a thin layer of it covers the nipple and areola will be applied.

Category

Treatment - Drugs

3

Description

Intervention group 2: Dexpanthone cream with trade name of Panthoderm made by Caspian Company, containing Pantothenic acid for 2 weeks 3 times a day immediately after milking, the amount of the drug so that a thin layer of it covers the nipple and areola will be applied.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Public health centers of Sanandaj city

Full name of responsible person

Dr Ronak Hemati

Street address

Abbas Abad street, Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research dupty of Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research dupty of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

kazhal Masoudin

Position

Masters of sciences student in midwifery

Other areas of specialty/work

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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