

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 Dspanthenol 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 Dspanthenol , 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

mshahnazi@tbzmed.ac.ir

##### 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 Dspanthenol 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

###### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Goltasht 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

##### Street address

Faculty of Nursing and Midwifery, South Shariati Street, Tabriz

##### City

Tabriz

##### Postal code

5177854616

##### Phone

+98 41 1447 4467

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##### Email

K\_masoudin@yahoo.com

##### Web page address

<http://nursing.tbzmed.ac.ir/>

### Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

Mahnaz Shahnazi

##### Position

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### Person responsible for updating data

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##### Full name of responsible person

Kazhal Masoudin

##### Position

Master of science student midwifery

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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*