

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Investigating the effect of Pistacia Atlantica ointment on nipple pain intensity and improvement of nipple fissure among visited breast feeding women in health centers of Shahid Beheshti university of Sciences in 1394

#### Protocol summary

##### Summary

The aim of this randomized clinical trial is to investigate the effect of Pistacia Atlantica ointment on nipple pain intensity and improvement of nipple fissure among visited breast feeding women in health centers of Shahid Beheshti University of Sciences. In this study, women suffering from nipple fissure and nipple pain who exclusively breast fed and get at least grade 3 through Storr scale; have healthy term infants; normal infant weight and without any mouth or palate or jaw or face anomaly; mother without any nipple malformation are entered to this study. Excluding criteria include the infant usage of a pacifier or feeding bottle; the infant gets infected to a disease; the mother makes use of milking machine or plastic nipple; the mother gets infected to mastitis, breast abscesses or fungal infection of the breast and use of the proposed treatment less than three times a day. 100 sample will be assigned randomly into two groups: applying Pistacia Atlantica ointment or control group (expressed breast milk). In the intervention group mothers apply an amount of Pistacia Atlantica ointment on nipple and Areola after feeding three times a day for 7 days. Mothers in control group apply 3-4 drops of their breast milk on nipple and areola after each feeding for 7 days and allow the nipples to air dry. At the beginning two groups will receive correct feeding technique. Storr scale and Numerical Rating Scale is completed before the study, on day 3 and on day 7 after the study by the investigator to evaluate nipple fissure and nipple pain intensity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015080723535N1**

Registration date: **2015-11-24, 1394/09/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-11-24, 1394/09/03

##### Registrant information

###### Name

Nayereh Asadi

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 23871

###### Email address

asadi-nayereh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

research and technology department of Shahid Beheshti University of Medical Sciences, Tehran

##### Expected recruitment start date

2015-08-17, 1394/05/26

##### Expected recruitment end date

2015-12-18, 1394/09/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Pistacia Atlantica ointment on nipple pain intensity and improvement of nipple fissure among visited breast feeding women in health centers of Shahid Beheshti university of Sciences in 1394

#### Public title

the effect of Pistacia Atlantica ointment on nipple pain intensity and improvement of nipple fissure

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Entry criteria: Mothers suffering from nipple pain and nipple fissure who; get at least grade 3 through Storr scale; more than 18 years old; Iranian and live in Tehran; literate; singleton birth; term and healthy infant and exclusively breast fed; infant weight 2500 to 4000 grams; infant without any mouth or palate or jaw or face anomaly; mother without any identified mental disease; mother without any nipple malformation (flat or inverted nipples or any nipple malformation which is followed by burning or any history of nipple and areola operation in childhood); mothers don't suffer from known background diseases such as diabetes or any kind of internal\_surgical diseases; mothers who do not have any allergy to Pistacia Atlantica ointment. Excluding Criteria: During the study, the infant uses a pacifier or feeding bottle;The mother makes use of milking machine or plastic nipple; During the study, the infant gets infected to a disease; During the study, allergy to Pistacia Atlantica occurs; During the study the mother uses antibiotic;The mother gets infected to mastitis, breast abscesses or fungal infection of the breast; The mother does not desire to continue cooperation; Use of the proposed treatment less than three times a day; Use of the other treatments by the mother.

#### Age

From **18 years** old

#### 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)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Ethics Committee of the Faculty of Pharmacy and Nursing Midwifery of Shahid Beheshti U

##### Street address

Vali-Asr Avenue, Cross of Vali-Asr and Niayesh Highway, opposite to Rajaee Heart Hospital, Tehran, Iran

##### City

Tehran

##### Postal code

1985717443

##### Approval date

2015-07-21, 1394/04/30

##### Ethics committee reference number

SBMU2.REC.1394.10

## Health conditions studied

### 1

#### Description of health condition studied

nipple fissure

#### ICD-10 code

N64.0

#### ICD-10 code description

Fissure and fistula of nipple

## Primary outcomes

### 1

#### Description

reduction of nipple pain

#### Timepoint

before intervention, day 3 and day 7 after intervention

#### Method of measurement

using Numerical Rating Scale for measuring pain intensity

### 2

#### Description

improvement of nipple fissure

#### Timepoint

before intervention, day 3 and day 7 after intervention

#### Method of measurement

Storr scale to measure nipple fissure

## Secondary outcomes

### 1

#### Description

side effects of Pistacia Atlantica ointment

#### Timepoint

before intervention, day 3 and day 7 after intervention

## Method of measurement

examining and interviewing the patient

## Intervention groups

### 1

#### Description

1 gram of Pistacia Atlantica ointment (in 24 gram cans) will be rubbed to the nipple and areola three times a day for 7 days.

#### Category

Treatment - Drugs

### 2

#### Description

In the control group 2-3 drops of expressed breast milk will be rubbed to the nipple and areola after each feeding and then allow to air dry for seven days.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University of Sciences, health center of the North of Tehran (Nader)

##### Full name of responsible person

Nayereh Asadi

##### Street address

NO. 57, Shahid Esfandany street, Jashnvareh street, second square of Tehranpars, Tehran, Iran

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University of Sciences, health center of the North of Tehran (Samarghandi)

##### Full name of responsible person

Nayereh Asadi

##### Street address

No. 175, between 206 and 212 street, Ordibehesht square, Farjam street, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

research and technology department of Shahid Beheshti University of Medical Sciences, Tehran

##### Full name of responsible person

Dr. Afshin Zarghi

#### Street address

A'rabi street, near Shahid Ayatollah Taleghani hospital, Yemen street, Shahid Chamran highway, Tehran, Iran

#### City

Tehran

#### Grant name

-

#### Grant code / Reference number

-

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

Yes

#### Title of funding source

research and technology department of Shahid Beheshti University of Medical Sciences, Tehran

#### 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

Shahid Beheshti University of Sciences, Tehran

##### Full name of responsible person

Nayereh Asadi

##### Position

Master of Science university student of Midwifery

##### Other areas of specialty/work

##### Street address

Tehran - Shahid Chamran Highway Yemen street , A'rabi Street, near Shahid Ayatollah Taleghani hospital, Shahid Beheshti University of Medical Sciences, Tehran

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##### Email

asadi\_nayereh@sbmu.ac.ir

nayereh.asadi62@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Sciences, Tehran

**Full name of responsible person**

Dr. Nourossadat Kariman

**Position**

Assistant Professor, PhD of Reproductive Health

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

A'rabi street, near Shahid Ayatollah Taleghani hospital, Yemen street, Shahid Chamran highway, Tehran, Iran

**City**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Sciences, Tehran

**Full name of responsible person**

Nayereh Asadi

**Position**

Master of Science university student of Midwifery

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

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**Phone**

+98 21 23871

**Fax****Email**

asadi\_nayereh@sbmu.ac.ir nayereh.asadi62@gmail.com

**Web page address****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*