

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

City

Tehran

Postal code

۱۹۹۶۸۳۵۱۱۹

Phone

+98 21 23871

Fax

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

Tehran

Postal code

۱۹۹۶۸۳۵۱۱۹

Phone

+98 21 23871

Fax**Email**

n_kariman@sbmu.ac.ir n_kariman@yahoo.com

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

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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