

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Investigating the effect of Ziziphus Jujube fruit lotion improvement of nipple fissure in referring women to gynecological centers Ghaem Hospital of related to Kerman Medical Science university on 2015

#### Protocol summary

##### Summary

The aim of this randomized clinical trial is to investigate the effect of Ziziphus Jujube Fruit lotion improvement of nipple fissure in referring women to Gynecological centers Ghaem Hospital of related to Kerman Medical Science University. In this study, women suffering from nipple fissure and nipple pain who exclusively breast fed ; 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 five times a day. 100 sample will be assigned randomly into two groups:applying Ziziphus Jujube Fruit lotion or control group (expressed breast milk). In the intervention group mothers apply an amount of Ziziphus Jujube Fruit lotion on nipple and Areola after feeding five times a day for 10 days. Mothers in control group apply 3-4 drops of their breast milk on nipple and areola after each feeding for 10 days and allow the nipples to air dry. At the beginning two groups will receive correct feeding technique. Amir scale, the existence of nipple discharge and Numerical Rating Scale is completed before the study, on day 7 and on day 14 after the study by the investigator to evaluate nipple fissure intensity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015121225490N1**

Registration date: **2016-01-22, 1394/11/02**

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

Last update:

Update count: **0**

##### Registration date

2016-01-22, 1394/11/02

##### Registrant information

###### Name

Nasim Shahrahmani

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3355 2011

###### Email address

nasim.rahmani1368@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Ziziphus Jujube fruit lotion improvement of nipple fissure in referring women to gynecological centers Ghaem Hospital of related to Kerman Medical Science university on 2015

**Public title**

The effect of Ziziphus Jujube fruit lotion improvement of nipple fissure

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Entry criteria: Mothers suffering from nipple pain and nipple fissure who; more than 18 years old; Iranian; 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 Ziziphus Jujube fruit lotion. 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 Ziziphus Jujube fruit lotion 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 five 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)**

Double 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 Rajaei Heart Hospital, Tehran, Iran

**City**

Tehran

**Postal code**

1985717443

**Approval date**

2015-05-31, 1394/03/10

**Ethics committee reference number**

SBMU.REC.1394.43

**Health conditions studied****1****Description of health condition studied**

Nipple fissure

**ICD-10 code**

N64.0

**ICD-10 code description**

درد و شقاق نوک پستان

**Primary outcomes****1****Description**

Reduction of nipple pain

**Timepoint**

Before intervention, day 7 and day 14 after intervention

**Method of measurement**

Using Numerical Rating Scale for measuring pain intensity

**2****Description**

Reduction of nipple wound discharge

**Timepoint**

Before intervention, day 7 and day 14 after intervention

**Method of measurement**

Visual analog

**3****Description**

The improvement of nipple fissures

**Timepoint**

Before intervention, day 7 and day 14 after intervention

**Method of measurement**

Measure the severity of damage, by Amir scale

**Secondary outcomes****1****Description**

Side effects of ziziphus jujube fruit lotion

**Timepoint**

Before intervention, day 7 and day 14 after intervention  
**Method of measurement**  
Before intervention, day 7 and day 14 after intervention

## Intervention groups

### 1

#### Description

0.5 ml Ziziphus Jujube fruit lotion will be rubbed to the nipple and areola five times a day for 10 days

#### Category

Treatment - Drugs

### 2

#### Description

In the control group 4 drops of expressed breast milk will be rubbed to the nipple and areola after each feeding and then allow to air dry for 10 days.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital Bardsir, Kerman University of Medical Sciences

##### Full name of responsible person

Nasim shahrahmani

##### Street address

Azadegan Blvd, Bardsir City, Kerman

##### City

Bardsir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sponsor 1 research and technology department of Shahid Beheshti University of Medical Sciences, Teh

##### 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

Sponsor 1 research and technology department of Shahid Beheshti University of Medical Sciences, Teh

#### 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

Nasim Shahrahmani

##### Position

Master of Science university student of Midwifery

##### Other areas of specialty/work

##### Street address

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

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+98 21 23871

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0

##### Email

Nasim.Shahrahmani@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

Sedigheh Amir Ali Akbari

##### Position

Academic Faculty Member

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Web page address**

0

## 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*