Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

The aim of this randomized clinical trial is to investigating the effect of Ziziphus Jujube Fruit lotion improvement of nipple fissure in referring women to Gynecological centeres Ghaem Hospital of related to Kerman Medical Sience 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 begining 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 Rajaee 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 centeres Ghaem Hospital of related to Kerman Medical Sience 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 Rajaee 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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sedigheh Amir Ali Akbari

Position

Academic Faculty Member

Other areas of specialty/work

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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