

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of Fenugreek seeds and Fennel herbal tea on Signs of adequate breast milk in mothers with baby girl 0-4 months

Protocol summary

Summary

This research is a randomized clinical trial that performed with 2 intervention group and a control group. Mainly aim of the study is to determine the effect of herbal tea fenugreek seed and fennel on breast feeding. Through random sampling 129 Mother with baby girl 0-4 months will be divide in two intervention group and one control group with Double-blind. The inclusion criteria includes: Infant girls 0 to 4 months were born between 37-42 weeks and is able to sucking milk natural! Baby and mother with no underlying disease that is causing the contraindications are breast-feeding! Mother did not use formula and Galactagogue and consumes a diet with high in dairy products. The exclusion criteria includes: unwilling to continue participate in research: the use of any chemical drugs or herbal medicines increases milk during the study. Sampling starts on 10/15/92. The samples will be entering in study with a demographic and Breastfeeding questionnaire. To assess the situation before the intervention, a follow-up form will be given to the mother for 2 days and she will be asked to record the frequency of urinary excretion, Frequency of defecation and frequency of infant feeding in 24 hours. Weight, height and head circumference will be measured and recorded by researcher. The first intervention group will receive Herbal tea containing 7/5 g powder of Fennel seed +3 grams of powder ordinary tea three times a day, The second intervention group will receive Herbal tea containing 7/5 g powder of Fenugreek seed +3 grams of powder ordinary tea three times a day and the control group will receive Herbal tea containing 3 grams of powder ordinary tea three times a day. Drugs will be given weekly for 4 weeks and in the each visit of mother, weight, height and head circumference will be measured and recorded by researcher. A follow-up form will be given to mother for every week and she will be asked to record the frequency of urinary excretion, frequency of defecation and frequency of infant feeding in 24 hours. During the 4-week follow-up and at the end of 4 weeks,

Different signs of sufficient breast milk in Interventions and control groups will be assessed by using the follow-up form and measuring growth parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312102751N10**

Registration date: **2013-12-19, 1392/09/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-19, 1392/09/28

Registrant information

Name

Masoomeh Kheirkhah

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8247 1000

Email address

kheirkhah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-01-05, 1392/10/15

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Fenugreek seeds and Fennel herbal tea on Signs of adequate breast milk in mothers with baby girl 0-4 months

Public title

The effect of Fenugreek seeds and Fennel herbal tea on Signs of adequate breast milk in mothers with baby girl 0-4 months

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria includes: Infant girls 0 to 4 months were born between 37-42 weeks and is able to sucking milk natural! Baby and mother with no underlying disease that is causing the contraindications are breast-feeding; Mother did not use formula and Galactagogue and consumes a diet with high in dairy products. The exclusion criteria includes: unwilling to continue participate in research;The use of any chemical drugs or herbal medicines increases milk during the study.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **129**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University Of Medical Sciences

Street address

Central Apartment Of Tehran University Of Medical Sciences, Keshavarz blvd

City

Tehran

Postal code**Approval date**

2013-11-23, 1392/09/02

Ethics committee reference number

1913/130/92/3

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

Breast feeding

ICD-10 code

P92.8

ICD-10 code description

Other feeding problems of newborn

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

Frequency of defecation

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Follow-up form

2**Description**

Frequency of infant feeding

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Follow-up form

3**Description**

Weight infant

Timepoint

Weekly for 4 weeks

Method of measurement

Weight scale

4**Description**

Height infant

Timepoint

Weekly for 4 weeks

Method of measurement

Meter

5**Description**

Head circumference of infants

Timepoint

Weekly for 4 weeks

Method of measurement

Meter

6

Description

Frequency of urinary excretion

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Follow-up form

Secondary outcomes

empty

Intervention groups

1

Description

Herbal tea containing 7/5 g powder of Fenugreek seed +3 grams of powder ordinary tea three times a day for 4 weeks

Category

Treatment - Drugs

2

Description

Herbal tea containing 7/5 g powder of Fennel seed +3 grams of powder ordinary tea three times a day for 4 weeks

Category

Treatment - Drugs

3

Description

Pelasebo Herbal tea containing 3 grams of powder ordinary tea three times a day for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Southern Tehran

Full name of responsible person

Vida Ghasemi

Street address

Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Younesian

Street address

Central Building of Tehran University of Medical Sciences, the Qods Street, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

School of Nursing and Midwifery Tehran University of Medical Science

Full name of responsible person

Masooome Kheirkhah

Position

Ms Midwifery/Master of Science

Other areas of specialty/work

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Person responsible for updating data

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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