

# 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**

**Street address**

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**Person responsible for updating data**

**Contact**

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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*