Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative Study on the Effect of “Honey and Fennel”, “Honey and“Fenugreek”, “Fennel”, and “Fenugreek” on Quality of Breastfeeding

Protocol summary

Study aim
Comparison of effect of "honey and fennel", "honey and fenugreek", "fennel" and "fenugreek" on quality of lactation

Design
Clinical trial, double-blinded, randomized, with four parallel groups

Settings and conduct
Sampling will perform in 2 selected health centers of Tehran. Participants will complete a personal information questionnaire, and breastfeeding success questionnaire. Weight, height and head circumference of the infants will measured. They will then randomly divided into four groups of 50 people (Fennel and honey composition group, Fenugreek and Fennel composition group, Fennel group, Fenugreek group). All Participants will receive the same medication (drop). These drugs are coded by the manufacturer. These codes are not clear to the participants, researchers, and controllers. Each of the 4 groups consumed 30 drops daily in 3 times for 4 weeks. During the intervention, infant growth will be assessed by measuring height, weight, head circumference and completed the lactation success questionnaire every 2 weeks. Then the data obtained in three stages (before and during the intervention) were used for statistical analysis. Drug side effects are also determined at the end of the intervention.

Participants/Inclusion and exclusion criteria
Healthy Women, no smoking, housewives, exclusive breastfeeding, normal BMI, during the first 1 to 5 months after delivery, milk deficiency, despite the correct method of breastfeeding, lack of breast problems, no taking any drugs interfering milk production.

Intervention groups
Fennel and honey composition group, Fenugreek and Fennel composition group, Fennel group, Fenugreek group.

Main outcome variables
Individual characteristics; Infant weight; Infant height; Head circumference of infant; The success of lactation; Drug side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120122008801N23**
Registration date: **2019-12-30, 1398/10/09**
Registration timing: **prospective**

Last update: **2019-12-30, 1398/10/09**
Update count: **0**

Registration date
2019-12-30, 1398/10/09

Registrant information

Name
Masoumeh Simbar

Name of organization / entity
Shahid Beheshti University for Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effect of “Honey and Fennel”, “Honey and“Fenugreek”, “Fennel”, and “Fenugreek” on Quality of Breastfeeding

Public title

Effect of Fennel, Fenugreek and their Combination with Honey on Lactation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy Women No smoking House wives Exclusive breastfeeding The mother has a normal body mass index (19.8-26 kg / m 2) During the first 1 to 5 months after delivery There is a milk deficiency, despite the correct method of breastfeeding The woman should not have breast problems such as abscesses, nipple dislocations, and low or non-glandular tissue of the breast The mother should not take any drugs that interfere with the production of milk and antibiotics Recent history of normal delivery of a single-term baby weighing between 2.5 and 4 kg The infant has no malformations, illness, or malnutrition problem requiring hospitalization

Exclusion criteria:

Any mental illness in the mother Any physical illness that disrupts breastfeeding, such as liver disease, cancer and mammalian problems in the mother Mother taking dopamine antagonist drugs (such as domperidone, metoclopramide, rospridone, phenothiazine) The mother stops breastfeeding for any reason

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by simple randomization using a random number table. 200 participants are divided into four groups of 50 people by simple randomization method. Includes: 1- Fennel and honey composition group, 2- Fenugreek and Fennel composition group, 3- Fennel group, 4- Fenugreek group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in all four groups will receive the same medication (in the form of a drop). These drugs are coded by the manufacturer of the drugs. These codes are not clear to the participants, researchers, and controllers. At the end, the codes will be specified for data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the researchers, after obtaining the necessary permits for the research, will perform sampling in two selected health centers of Tehran (Nader and Sahebzaman). In these centers, sampling is done by random allocation. Participants, after completing a written consent form, will complete a personal information questionnaire, and a breastfeeding success questionnaire. The infant's characteristics are also determined and weight, height and head circumference of the baby are measured. They were then randomly divided into four groups of 50 each. Includes: 1- Fennel and honey composition group 2- Fenugreek and Fennel composition group 3- Fennel group 4- Fenugreek group. These four groups take the herbal medicine in drops. Each of the four groups consumed 30 drops daily in three servings for four weeks. During the intervention, infant growth information will be assessed by measuring height, weight, head circumference and lactation success rate by completing the lactation success questionnaire every two weeks. Then the data obtained in three stages (before the intervention and during the intervention during the two follow-up intervals) were used for statistical analysis and comparison by SPSS software. Drug side effects are also determined at the end of the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده های داروسازی، پرستاری و مامایی- دانشگاه علوم پزشکی شهید بهشتی

Street address

Iran National commitee for Ethics in Biomedical Research

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Tehran

Province

Tehran

Postal code

1996835119

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398

Health conditions studied

1

Description of health condition studied
The success of lactation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Lactation
Timepoint
Measurement of infant's weight, height, and head circumference and information on lactation success at baseline (before beginning) and 14 and 28 days after taking compounds in all four groups.
Method of measurement
Measuring infant growth by measuring infant's weight, height and circumference, measuring lactation success by completing the Lactation Success Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: Fennel and honey composition group, Second intervention group: Fenugreek and fennel combination group, Third intervention group: Fennel group, Fourth intervention group: Fenugreek group.p:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Two health centers in Tehran (Nader and Sahebzaman)
Full name of responsible person
Masoumeh Simbar
Street address
Cross of Hashemi high way and ValiAsr Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Protocol and data files
When the data will become available and for how long
After publishing the article
To whom data/document is available
For Journal reviewers and the readers of the article if they need
Under which criteria data/document could be used
If they asked
From where data/document is obtainable
Midwifery and Reproductive Health Rese4arch Center Shahid Beheshti University of Medical Sciences
What processes are involved for a request to access data/document
email to researchers
Comments