

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of fenugreek on milk volume and prolactin level in mothers of premature infants: A randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of fenugreek on milk volume and prolactin level in mothers of premature infants

Design

A concealed, randomized, triple blind, controlled clinical trial with a parallel group design of 68 women, phase 3.

Settings and conduct

This study will be performed on 68 postpartum mothers whose preterm delivery is under 32 weeks and whose infants are hospitalized in Al-Zahra and Taleghani educational and medical centers in Tabriz. Mothers will be assessed according to the eligibility criteria and if they have criteria and have willingness to participate in the study, the written informed consent will be obtained and primary evaluations will be conducted. Participants will be assigned into two groups of fenugreek capsule recipient and placebo recipient using block randomization method with block sizes of 4 and 6 and allocation ratio of 1:1.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with preterm infants under 32 weeks on the fifth day after delivery, Ability to breastfeed
Exclusion criteria: Allergy to fenugreek, Asthma disease, Endocrine problems

Intervention groups

The intervention group will receive a capsule containing 500 mg of fenugreek powder and the control group will receive a placebo capsule with the same dose three times a day for two weeks.

Main outcome variables

The main outcome variables are milk volume and prolactin level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N62**

Registration date: **2021-01-24, 1399/11/05**

Registration timing: **prospective**

Last update: **2021-01-24, 1399/11/05**

Update count: **0**

Registration date

2021-01-24, 1399/11/05

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-28, 1399/11/09

Expected recruitment end date

2021-05-30, 1400/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fenugreek on milk volume and prolactin level in mothers of premature infants: A randomized controlled clinical trial

Public title

The effect of fenugreek on milk volume and prolactin level in mothers of premature infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers with preterm infants under 32 weeks on the fifth day after delivery Having a minimum literacy Ability to visit the mother of the hospitalized infant on a daily basis Ability to breastfeed
Exclusion criteria:
 Allergy to fenugreek Any abnormalities in growth or breast surgery Endocrine problems such as diabetes or thyroid disorder Participate in other interventional study Having asthma

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in the study will be assigned to two groups (one group receiving of oral fenugreek capsule three times a day for two weeks and one group receiving placebo with the same protocol) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the drug and placebo will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2021-01-17, 1399/10/28

Ethics committee reference number

IR.TBZMED.REC.1399.946

Health conditions studied

1

Description of health condition studied

Premature infants

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Milk volume

Timepoint

7 days after the start of the intervention and 1 day after the end of the intervention

Method of measurement

Using the pump

2

Description

Serum prolactin levels

Timepoint

One day after the intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Infant weight
Timepoint
One day after the intervention
Method of measurement
Scale

2

Description
Satisfaction of mothers
Timepoint
One day after the intervention
Method of measurement
Checklist

3

Description
Exclusive breastfeeding
Timepoint
One day after the intervention
Method of measurement
Checklist

Intervention groups

1

Description
The intervention group will receive oral capsules containing 500 mg fenugreek powder three times a day (One tablet each time with breakfast, lunch and dinner) made by Pharmacy school of Tabriz University of Medical Sciences. The duration of treatment will be two weeks.
Category
Treatment - Drugs

2

Description
The control group will receive oral capsules containing 500 mg starch three times a day (One tablet each time with breakfast, lunch and dinner) made by Pharmacy school of Tabriz University of Medical Sciences. The duration of treatment will be two weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Maryam Vaezi
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province

East Azarbaijan
Postal code
5138947977
Phone
+98 41 3478 5229
Email
mahsa.rouhi.mid@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3335 7310
Email
mahsa.rouhi.mid@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahsa Rouhi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3478 5229

Email

mshsa.rouhi.mid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghfourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

9876598765

Phone

+98 41 3478 5229

Email

mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghfourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3478 5229

Email

mirghafourvandm@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential .

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available