

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the Effect oral drop Cumin cyminum and Nettle Seed on Breast Milk Sufficiency

Protocol summary

Study aim

Comparison of the Effect oral drop Cumin cyminum and Nettle Seed on Breast Milk Sufficiency

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment. As the study group and the researcher and statistical analyst, none of the persons in the studied groups are not aware of the combination of the drugs. The study, after approving and obtaining permission from the ethics committee and the necessary permissions, is carried out on 120 nursing mothers who are under study in west health centers affiliated with Iran University of Medical Sciences. Based on Excel Soft ware, mothers are divided in three Groups. Randomly: Cumin cyminum, Nettle, Placebo.

Participants/Inclusion and exclusion criteria

Babies 10 to 15 days between 37 to 42 weeks have been born. To be able to suck mother's breast naturally. The baby and the mother don't have any underlying and known illness. mother never has used milk powder and milk increasers. Have not used tobacco. The mother don't use herbal medicine or herbal supplement before studying.

Intervention groups

Intervention group: Group 15 ml oral drops Cumin three times a day for 28 days Intervention group: Group 15 ml oral drops of Nettle three times a day for 28 days Control group: Group 15 ml oral drops placebo three times a day for 28 days

Main outcome variables

Weight of infant The number of excrement The number of passing urine The number of breast feeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180609040022N1**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **retrospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Mahnaz Shafikhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6620 9219

Email address

m.shafikhani1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-15, 1396/11/26

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2018-02-15, 1396/11/26

Actual recruitment end date

2018-06-10, 1397/03/20

Trial completion date

empty

Scientific title

Comparison of the Effect oral drop Cumin cyminum and Nettle Seed on Breast Milk Sufficiency

Public title

Effect of Cumin cyminum and Nettle drop on Breast feeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Babies 10 to 15 days between 37 to 42 weeks have been born. To be able to suck mother's breast naturally. The baby and the mother don't have any underlying and known illness. mother never has used milk powder and milk increasers. Have not used tobacco.

Exclusion criteria:

The mother used herbal medicine or herbal supplement before studying.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers were randomly divided into three groups (A) and group (B) and group (C) by random sampling with excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Three arm parallel group randomized trial with blinded postoperative care and outcome assessment. so that the study group and researcher are not aware of any individuals located in the studied groups. Mothers were randomly divided into three groups (A) Cumin cyminum and group (B) Nettle and (C) Placebo by random sampling with excel software.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

No. 212 , Seyedalshohada Ave., Valiasr Town

City

Tehran

Province

Tehran

Postal code

1375814849

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.IUMS.REC 1396.32068

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

The number of excrement

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Following form

2

Description

The number of breast feeding

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Following form

3

Description

The number of urine pass

Timepoint

Within 24 hours for 4 weeks

Method of measurement

Following form

4

Description

Infant weight gain

Timepoint

Every 2 weeks for 4 weeks

Method of measurement

Following form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15ml oral drops Cumin cyminum three times aday for 28 days

Category

Treatment - Drugs

2

Description

Intervention group: 15ml oral drops Nettle three times a day for 28 days

Category

Treatment - Drugs

3

Description

Control group: 15 ml oral drops placebo three times a day for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

West health centers affiliated with Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shafikhani

Street address

Zandiye Ave., Yaft abad Blvd

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakooti

Street address

Hemmat road., Iran University of Medical Sciences

City

Tehran

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Postal code

1375813588

Phone

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Email

M.shafikhani1992@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shafikhani

Position

Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Full name of responsible person

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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

There was no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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