Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 on120 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
Babies10 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 ilness. mother never has used milk powder and milk Increasers. Have not used tobacco. The mothe don't used 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: Group15 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:
Babies10 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 ilness. 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 randomaly divided into three group (A) and group(B) and group (C) by random samplingwith excel soft ware.
Blinding (investigator's opinion)
Double blinded
Blinding description
Three arm parallel group randomised trail with blinded postoperative care and outcome assissment. so that the study group and researcher are not aware of any individuals located in the studied groups. Mothers were randomaly divided into three groups (A) Cumin cyminum and group (B) Nettle and (C) Placebo by random sampling with excel soft ware.
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 ofurine pass
Timepoint
Within 24 hours for 4 weeks
Method of measurement
Followin 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
City
Tehran
Province
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Postal code
1375813588
Phone
+98 21 6620 9219
Email
M.shafikhani1992@gmail.com

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
+98 21 86601
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

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

Contact

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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