Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Pimpinella anisum herbal tea on milk volume in mothers and weight gain of preterm infant

Protocol summary

Study aim
Comparison weight gain of preterm infant and milk volume of mother in study groups

Design
Clinical trial study with intervention, placebo and control groups. Participants will be assigned in 6 blocks.

Settings and conduct
It is randomized clinical trail study with 3 group on 135 lactating women with preterm infant will be performed in NICU Akbarabadi hospital. Interventional group will receive 2 gr dry herbal tea of anisum in addition 1gr black tea and placebo group will receive 3 gr black tea. Mothers will consume 3 times in day of tea bag during 1 week. Mothers put 1 tea bag in glass and add 150 ml water on it and after 10 minute will drink.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mothers interest to exclusive breastfeeding, mothers interest to pumping breast, have minimum 18 years old, have normal body mass index, present of mother in hospital in special room for mother and neonate, preterm infant with gestational age less than 32 weeks, Infant hospitalization in NICU fed with NG tube. Exclusion criteria: Use of cigarette, alcohol and drugs, use of any galactogogue and complementary drug, affliction of mother to infectious transferable diseases from lactating such as HIV and active pulmonary Tuberculosis, history of infertility, diabetic mother, mother use of anticoagulation, mothers with cancer related to estrogen, mother with psychological disorder, lack of breast growth in prenatal period, performance of breast surgery, existence of some illness of mother such as mastectomy, inverted nipple, abscess, and infection mastitis, existence of congenital anomalies such as harelip and cleft palate, twin neonates.

Intervention groups
The Pimpinella anisum tea group will receive 2 grams of dried anise plant plus 1 gram of black tea and the placebo group will receive tea containing 3 grams of dried black tea.

Main outcome variables
Increased breast milk volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180427039436N9**
Registration date: **2021-04-14, 1400/01/25**
Registration timing: **prospective**

Last update: **2021-04-14, 1400/01/25**
Update count: **0**

Registration date
2021-04-14, 1400/01/25

Registrant information

Name
Leila Amiri Farahani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4365 1139

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-24, 1400/03/03

Expected recruitment end date
2021-09-25, 1400/07/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Pimpinella anisum herbal tea on milk volume in mothers and weight gain of preterm infant

Public title
The effect of Pimpinella anisum herbal tea on milk volume in mothers and weight gain of preterm infant

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Mothers interest to exclusive breastfeeding Mothers interest to pumping breast with electronic pumping from third day of postpartum Have ability to read and write Have minimum 18 years old Have normal body mass index from 18.5 to 24.9 kg/m2 Present of mother in hospital in special room for mother and neonate on duration of study Preterm infant with gestational age less than 32 weeks Infant hospitalization in NICU fed with NG tube

Exclusion criteria:
Use of cigarette, alcohol and drugs Use of any galactogogue and complementary drug Affiliction of mother to infectious transferable diseases from lactating such as HIV and active pulmonary Tuberculosis History of infertility Diabetic mother Mother use of anticoagulation Mothers with cancer related to estrogen Mother with psychological disorder based on mother's self-report Lack of breast growth in prenatal period Performance of breast surgery Existence of some illness of mother such as mastectomy, inverted nipple, abscess, and infeection mastitis Existence of congenital anomalies such as harelip and cleft palate Twin neonates

Age
From **8 months** old to **8 months** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
sample will be intered continuously in study and will be randomized in 6 blocks with 3 groups in parallel arms in interventional, placebo and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
There is no possibility of blinding in the present study due to having a control group and only to increase the accuracy of the study, the researcher will not know the content of herbal teas given to individuals in each group.

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 sciences

Street address
Tehran, Valiaasr ave, Rashid yasami Ave, infront of Khatamol anbiaa hospital

City
Tehran

Province
Tehran

Postal code
1981111198

Approval date
2021-03-14, 1399/12/24

Ethics committee reference number
IR.IUMS.REC.1399.1417

Health conditions studied

1

Description of health condition studied
The effect of Pimpinella anisum herbal tea on milk volume in mothers and weight gain of preterm infant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determination of milk volume in mothers

Timepoint
1,2,3,4,5,6 and 7 days of study measurement of milk volume in mothers

Method of measurement
measurement of milk volume in mothers through Sweetheart medela

Secondary outcomes

1

Description
Determination of weight gain of preterm infant

Timepoint
0 days of study (before study) third days of study and

seventh days of study measurement of weight gain of preterm infant

Method of measurement

Measurement of weight of preterm infant through seca scale production of Germane county

Intervention groups

1

Description

Intervention group: The intervention group will receive Pimpinella anisum tea containing 2 grams of dried anise plant plus 1 gram of black tea and the placebo group will receive tea containing 3 grams of dried black tea.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar abadi hospital

Full name of responsible person

Sona Khalili

Street address

Tehran, Valiaasr ave, Rashid yasami Ave, infront of Khatamol anbiaa hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Shahid hemat highway, Direction2

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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

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

Lelila Amirifarahani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Amirifarahani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Latest degree
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Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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