Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effects of oral consumption of Foeniculum Vulgare Mill capsule on some indicators of neonatal health and prolactin level in over weight or obese lactating mothers

Protocol summary

Summary

This study is about"evaluation of the effects of oral consumption of Foeniculum vulgare Mill capsule on some indicators of neonatal health and prolactin level in over weight or obese lactating mothers referred to health and therapeutic centers in shiraz 2015".In this single blind randomized clinical trial the age of neonatal is 2 to 6 weeks.This investigation contains two groups:1-Examination group with consumption 3 gram oral powder of Foeniculum vulgare mill in 6 capsules daily.2-control group with consumption 3 gram oral powder of Starch in 6 capsules daily.The mothers will be receive medicines for 30 days.The study will be done on 66 persons after obtaining testimonial and filling questionnaire demographic.The level of prolactin and indicators of neonatal health include:Length,weight,head circumference will measure and compare before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072623347N1**
Registration date: **2015-09-27, 1394/07/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-27, 1394/07/05

Registrant information

Name
Sareh Saeidjou
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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stud2471686214@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-08-09, 1394/05/18

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of oral consumption of Foeniculum Vulgare Mill capsule on some indicators of neonatal health and prolactin level in over weight or obese lactating mothers

Public title

The effects of Foeniculum Vulgare Mill on indicators of neonatals health and serum prolactin level

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Exclusive breastfeeding by lactating mothers ;Body mass index 25 and higher(According to the first trimester of pregnancy); term and single Delivery;two to six weeks after delivery;The mother complain about the lack of milk despite correct methods

of breastfeeding; mother Age : 18-35;monthly cycle of period is not starting after delivery;Not using hormonal contraception(mini pills) Exclusion criteria:The presence of mental illness;Liver Disease and Cancer;Consumption of dopamine antagonist drugs(Domperidone,Metoclopramide,Phenothiazine);Cessation of breastfeeding For whatever reason;The occurrence of any event during the study period;Dissuasion from participating in the study;Breast surgery and Removal of all or part of the breast or mastectomy;Breast plastic surgery;Babies with special problems that Who can not drink milk(Such as cleft lip or palate);Allergy to carrots, celery or other plants Apiaceae family;Sensitivity to drug;Use of herbal medicines;Squeeze of milk.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee

Street address
Zand Street, Shiraz

City
Shiraz

Postal code
Iran

Approval date
2015-08-04, 1394/05/13

Ethics committee reference number
IR.SUMS.REC.1394.74

Health conditions studied

empty

Primary outcomes

1

Description
Serum Prolactin Level

Timepoint
before intervention,30 days after intervention

Method of measurement
Elisa kit, Elisa Rider System

Secondary outcomes

1

Description
Height,Weight And Head Circumference

Timepoint
before intervention and 30 days after intervention

Method of measurement
Tape Measure(Meter),Balance

Intervention groups

1

Description
Intervention group:6 capsules of Foeniculum vulgare mill daily(3gram per day) for 30 days

Category
Treatment - Drugs

2

Description
control group:placebo for 30 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers of Shiraz University of Medical Sciences

Full name of responsible person
Sareh Saeidjou

Street address
Zand Street,Shiraz,Fars

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

GHolamreza Hatam

Street address

Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sareh Saeidjou

Position

Master Student In Midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty