

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of fennel powder on serum prolactin in nursing mothers and weight gain in newborns with the effect of domperidone and placebo

Protocol summary

Study aim

1-Determination and comparison of serum prolactin levels in nursing mothers before intervention and 14 days after taking medication. 2- Determining the weight of neonates participating in the study at the birthday, day 14 and day 28

Design

Three arm parallel group with 50 people, randomized trial with double-blinded

Settings and conduct

The serum levels of prolactin in nursing mothers at the beginning of the study and before taking drugs in Imam Sajjad Hospital in Yasuj, and 14 days after taking medications, were measured by ELISA method using Probind PRL kit (ELISA) from Saman Tajhiz Noor Co. from the blood sample. Will be recorded. The weight gain of the baby, which is an indirect indication of the amount of breast milk, is measured by weighing the infant at birth, on the 14th and 28th day after birth, with a Seca725 digital scanner with a precision of 5g. Will be recorded. The changes in serum prolactin and the weight gain of the baby will be compared in these three groups.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1.Mothers with newborn babies 2.No contraindication for breastfeeding 3.Healthy baby 4.No having a history of cardiovascular disease in the mother 5.Obtain informed and written consent of patients 6.Birth weight exceeding 2500 grams Non-inclusion criteria: 1.Mother's unwillingness to continue lactation 2.Significant side effects

Intervention groups

1- Domperidone consumer group 2- Fennel powder consumer group 3- The placebo group

Main outcome variables

Mother's age, Newborn sex, Prolactin serum level of the mother, Newborn weight Type of delivery, Number of deliveries, Consumable medicine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161103030684N2**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **retrospective**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 000

Email address

keshtkari@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of fennel powder on serum prolactin in nursing mothers and weight gain in newborns with the effect of domperidone and placebo

Public title

The effect of fennel powder on serum prolactin levels in nursing mothers and newborns weight gain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers have a newborn baby No contraindication for breast feeding Well baby Not having a history of cardiovascular disease in the mother Obtain informed and written consent of patients Birth weight, more than 2500 grams

Exclusion criteria:

Age

From **1 day** old to **2 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation was done with the help of lottery so that the number of people in three groups of intervention and control of the paper was inscribed with the name of the group and placed in a container and by referring each patient one paper randomly selected and the person to the group Written in the paper.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is done single blind. This means that only patients who received the medication did not know.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasuj Research Ethic Committee

Street address

Blvd shahid mothahari ,Yasuj

City

Yasuj

Province

Kohgiluyeh-va-Boyrabad

Postal code

7591741417

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.YUMS.REC.1397.002

Health conditions studied

1

Description of health condition studied

Comparison the effect of Foeniculum Vulgare Miller (Fennel) on serum prolactin and newborn weight gain with the effect of Domperidone and placebo

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mother blood serum of prolactin. a weight of newborn,

Timepoint

A blood sample of mothers were taken before and 14 days after using the above drugs. The birth weight, weight of the 14th day and the 28th day were measured.

Method of measurement

blood serum levels of prolactin were measured in the laboratory. weight measured using digital scales

Secondary outcomes

1

Description

New born weight gain

Timepoint

At birth, 14 day and 28 day after birth

Method of measurement

By digital scale

2

Description

Change in prolactin level

Timepoint

Before taking of drug , 2 weeks later

Method of measurement

By laboratory

Intervention groups

1

Description

Intervention group: After explaining the different stages of the study by the program administrators and obtaining voluntary consent from the volunteers without any costs for medicine, examination or visitation, patients of 1th group received the capsule containing domperidone for 14 days and the level of serum prolactin before and after from the 14th day of taking the above medicine, blood samples were taken from them and blood serum was sent to the laboratory. The newborn weight at the birth time, the 14th day and the twenty-eighth day was measured using digital scales.

Category

Treatment - Drugs

2

Description

Intervention group: After explaining the different stages of the study by the program administrators and obtaining voluntary consent from the volunteers without any costs for medicine, examination or visitation, patients of 2nd group received the capsule containing fennel powder for 14 days and the level of serum prolactin before and after From the 14th day of taking the above medicine, blood samples were taken from them and blood serum was sent to the laboratory. The newborn weight at the birth time, the 14th day and the twenty-eighth day was measured using digital scales.

Category

Treatment - Drugs

3

Description

Control group: After explaining the different stages of the study by the program administrators and obtaining voluntary consent from the volunteers without any costs for medicine, examination or visitation, patients of this group received the placebo capsule for 14 days and the level of serum prolactin before and after from the 14th day of taking the above medicine, blood samples were taken from them and blood serum was sent to the laboratory. The newborn weight at the birth time, the 14th day and the twenty-eighth day was measured using digital scales.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam sajjad hospital of yasuj

Full name of responsible person

Ali keshtkari

Street address

Shahid jalil Blvd

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 0163

Email

a_keshtkari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali keshtkari

Street address

Shahid Motahari Blvd,yasuj medical sciences

City

yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

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Email

a_keshtkari@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Ali keshtkari

Position

assistant profesor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali keshtkari

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Ali keshtkari

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Email

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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

Because the study has ended before 11.10.1397

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable