Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Vitex Agnus Castus Extract on Blood Level of Prolactin & It,s Hormonal, Metabolic & Histological Effects in Comparison with Bromocriptin & Dostinex in Hyperprolactinemic Women

Protocol summary

Study aim
Evaluate the effect of Vitex agnus castus extract on blood level of prolactin & its Hormonal, Metabolic & histological effects in comparison with Bromocriptin & Dostinex in hyperprolactinemic women

Design
Non randomized, 3 arm parallel groups trial by physician. assessment by blind person, sample size 105, phase 2-3

Settings and conduct
Among women with hyperprolactinemia referring to treatment centers, about 105 persons selected and divided into three 35 persons groups: bromocriptine, dostinex and vitagnus for the 4 menstrual cycle، assessment personnel blinded.

Participants/Inclusion and exclusion criteria
Enter: women with hyperprolactinemia Age 18-45 Confirm letter of satisfaction Not enter: Pregnancy

Intervention groups
1.bromocriptine receiving group 2. dostinex receiving group 3. vitagnus receiving group

Main outcome variables
level of blood prolactin؛ level of blood total cholesterol؛ level of blood LDL؛ level of blood HDL؛ level of blood triglyceride؛ thickness of endometrium؛histological defference of endometrium؛ level of blood FSH day 9-12؛ level of blood estradiol day 9-12؛ level of blood LH day 12-14؛ level of blood midluteal progestrone day 14-17.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200118046171N1**
Registration date: **2020-02-03, 1398/11/14**
Registration timing: **retrospective**
Last update: **2020-02-03, 1398/11/14**
Update count: **0**

Registration date
2020-02-03, 1398/11/14

Registrant information

Name
Naiyereh Haerifar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3196 6522

Email address
naiyereh.haerifar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-09-22, 1395/07/01

Expected recruitment end date
2017-10-22, 1396/07/30

Actual recruitment start date
2016-09-22, 1395/07/01

Actual recruitment end date
2018-10-22, 1397/07/30

Trial completion date
2018-10-22, 1397/07/30

Scientific title
The Effect of Vitex Agnus Castus Extract on Blood Level of Prolactin & It,s Hormonal, Metabolic & Histological Effects in Comparison with Bromocriptin & Dostinex in Hyperprolactinemic Women

Public title
The Effect of Vitex Agnus Castus Extract on Blood Level of Prolactin & It,s Hormonal, Metabolic & Histological

Effects in Comparison with Bromocriptin & Dostinex in Hyperprolactinemic Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

women with hyperprolactinemia Age 18-45 confirm letter of satisfaction

Exclusion criteria:

Pregnancy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider

Sample size

Target sample size: **105**

Actual sample size reached: **103**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Personnel of laboratory, radiology & clinical care,was blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medical science faculty,Tabriz Branch, Islamic Azad University.

Street address

Islamic Azad university of Tabriz, Pasdaran Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5157944533

Approval date

2016-06-14, 1395/03/25

Ethics committee reference number

IR.IAU.TABRIZ.REC.1395.1

Health conditions studied

1

Description of health condition studied

Hyperprolactinemia.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood level of prolactin

Timepoint

One week before treatment,One, Two, Three & Four menstrual cycle after starting treatment

Method of measurement

sampling of blood serum

Secondary outcomes

1

Description

Total Cholesterol

Timepoint

Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles

Method of measurement

Vein Blood sampling

2

Description

LDL Cholesterol

Timepoint

Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles

Method of measurement

Vein Blood sampling

3

Description

HDL Cholesterol

Timepoint

Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles

Method of measurement

Vein Blood sampling

4

Description

triglyceride

Timepoint

Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles

Method of measurement

Vein Blood sampling

5

Description
Follicle stimulating hormone (FSH)
Timepoint
Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles
Method of measurement
Vein Blood sampling

6

Description
Luteinizing Hormone (LH)
Timepoint
Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles
Method of measurement
Vein Blood sampling

7

Description
Estradiol
Timepoint
Before Intervention and for 4 cycles with Intervention, Between 11-13 days of menstrual cycles
Method of measurement
Vein Blood sampling

8

Description
Progesterone
Timepoint
Before Intervention and for 4 cycles with Intervention, Between 17-22 days of menstrual cycles
Method of measurement
Vein Blood sampling

9

Description
Thickness of endometrium
Timepoint
Before Intervention and for 4 cycles with Intervention, Between 1-3 days of menstrual cycles
Method of measurement
Abdominal Sonography

Intervention groups

1

Description
Intervention group: Oral bromocriptine,as protocol:1-3 tablet daily (each tablet contents 2.5 mg bromocriptine mesylate), Iran Hormone, for 4 menstrual cycles
Category
Treatment - Drugs

2

Description
Intervention group:Oral Ḍostinex,as protocol:2-4 times weekly half a pill (each tablet contents 0.5mg Cabergoline),Italy PFIEZER ,for 4 menstrual cycls
Category
Treatment - Drugs

3

Description
Intervention group: Oral Vitagnus,2-4 tablet daily(each tablet contents 3mg extract of Vitex Agnus),Pour Sina, for 4 menstrual cycls
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz treatment centers
Full name of responsible person
Zahra Ghatreh Samani
Street address
medical faculty of islamic Azad university; Soleyman Khater Ave.
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naiyereh.haerifar@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Gholamhassan Vaezi
Street address
Department of microbiology, Karaj Branch, Islamic Azad University, Karaj,Iran
City
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Tehran
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51579445333
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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Naiyereh Haerifar

Position

student

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Ghatreh Samani

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Naiyereh Haerifar

Position

student

Latest degree

Master

Other areas of specialty/work

Physiology

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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 is not another information.

Study Protocol

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

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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