Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparative study of the effect of marticaria chamomilla syrup and cabergoline on hyperprolactinemia

Protocol summary

Summary

The aim of this study is to compare the effect of marticaria chamomilla syrup versus cabergoline in idiopathic hyperprolactinemia. This study is a randomized controlled trial. We include idiopathic hyperprolactinemia women between 18 to 45 years old whose disease has recently been diagnose and serum prolactin level is above25 µgr/L with asymptomatic or mild symptoms. Patient with liver failure, kidney failure, hypothyroidism, prolactinoma, pituitary and hypothalamus disease are not enrolled. Those patient who take any medication that is effective in prolactin secretion in the last three months and who has sensitivity to ergot derivatives are not entered in the study. A total of 158 patient are divided into two 79 member groups. One group is treated with syrup of marticaria chamomillaand the other with the cabergoline tablet for one month. At the beginig of the experiment and 30 days after the usage of drug serum prolactin level are measured and the results are compared across the two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122215891N1**
Registration date: **2014-06-20, 1393/03/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-06-20, 1393/03/30

Registrant information

Name

Marya Kabiri

Name of organization / entity

Traditional Medicine Faculty, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

From Traditional Medicine Faculty, Tehran University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of marticaria chamomilla syrup and cabergoline on hyperprolactinemia

Public title

hyperprolactinemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction; Female; Outpatients older than 18 years; Patient with asymptomatic or mild symptoms idiopathic hyperprolactinemia (menstrual disorders that are just starting with or without galactorrhea or without bothering galactorrhea alone); Serum prolactin level

above 25 µgr/L Exclusion criteria: Patients older than 45 years; Patient with liver failure; Patient with kidney failure; Patient with hypothyroidism; Taking medication such as haloperidol, phenothiazine, butyrophenone, monoamine oxidase inhibitor, fluoxetine, sulpiride, metoclopramide, domperidone, tricyclic antidepressants, opioid, estrogen, verapamil, reserpine, methyldopa, benzodiazepine, cimetidine, medroxolol drugs and any medication that is effective in prolactin secretion in the last three months; The use of warfarin; The use of sedating; Prolactinoma(micro or macro adenoma); Adrenal, pituitary and hypothalamus disease; Pregnant women; Women who plan to become pregnant; Breast feeding; Autoimmune disease such as lupus; Long- term menstural disorders; Bothering galactorrhea; Underlying disease such as diabetes, hypertension and cancer; History of hyperprolactinemia treatment in the last 6 months; The use of propranolol and vasoconstrictor drugs; Raynaud's disease; History sensitivity to ergot derivatives; History of stomach ulcers and gastrointestinal bleeding; Asthma; History of hay fever and allergic reaction to member of the compositae family such as yarrow, feverfew, artemisia, tansy

Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **158**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Faculty of Traditional Medicine, Tehran University of Medical Sciences
Street address
Keshavarz Blv Ghods St Tehran
City
Tehran
Postal code
Approval date
2014-04-09, 1393/01/20
Ethics committee reference number
130/45/93/د

Health conditions studied

1

Description of health condition studied
Hyperprolactinaemia
ICD-10 code
E 22.1
ICD-10 code description
Hyperprolactinaemia

Primary outcomes

1

Description
Serum prolactin level
Timepoint
Before and after the intervention
Method of measurement
Laboratory measurement

Secondary outcomes

1

Description
Side effects
Timepoint
During the treatment
Method of measurement
questionnaire and Physical exam

Intervention groups

1

Description
Medication administration (marticaria chamomilla syrup) 5 cc two times a day for 4 weeks.
Category
Treatment - Drugs

2

Description
Cabergoline 0.25 mg twice a week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Marya Kabiri

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica

Full name of responsible person

Dr. Minaei

Street address

Behesht Ave., Vahdat eslami St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica

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

Traditional Medicine Faculty, Tehran University of Medical Sciences

Full name of responsible person

Marya Kabiri

Position

Physician, PhD student

Other areas of specialty/work

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Web page address

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*