Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Fertility outcome of hyperprolactinemic infertile women undergoing induction of ovulation for intrauterine insemination (IUI): A comparison between Bromocriptine and Cabergoline

Protocol summary

Summary

The aim of this study was to compare the effects of bromocriptine versus cabergoline on pregnancy outcomes in hyperprolactinaemic infertile women. We included hyperprolactinaemic infertile women with or without galactorrhea (prolactin>20 ng/ml) and the major exclusion criteria were other causes of infertility in both couples and any treatment side effects. A total number of 183 infertile women with hyperprolactinemia undergoing intrauterine insemination (IUI) were randomly divided into two groups. Group A: 94 patients under the treatment of bromocriptine 2.5 mg BID and group B: 89 patients under the treatment of cabergoline 0.25 mg twice a week. Induction of ovulation was started when prolactin level became normal. Vaginal sonography was performed on the day 10th or 11th of cycle and according to the size and number of stimulated follicles, HMG was continued till at least 2 dominant follicles with size of >18 mm were seen. If this condition was not achieved, HMG was discontinued and it was restarted from the next cycle. IUI was performed 24-36 hours after swim-up method. Pregnancy was documented by transvaginal sonography, at 6-7 weeks of gestational age. Main outcome measurements were serum prolactin level, disappearance of galactorrhea, regulation of menses, side effects of both medication and the occurrence of pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806142420N1**
Registration date: **2009-10-25, 1388/08/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-10-25, 1388/08/03

Registrant information

Name
Seyed-Mohammad Fereshtehnejad
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2275 6035
Email address
mohammad@stu.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Shiraz University of Medical Sciences

Expected recruitment start date

2005-03-01, 1383/12/11

Expected recruitment end date

2007-03-01, 1385/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fertility outcome of hyperprolactinemic infertile women undergoing induction of ovulation for intrauterine insemination (IUI): A comparison between Bromocriptine and Cabergoline

Public title

Comparison of the effects of Bromocriptine and

Cabergoline on the occurrence of pregnancy in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Primary or secondary infertility, 2) Hyperprolactinemia with or without galactorrhea (prolactin>20ng/ml), 3) Normal HA except high prolactin level, normal HSG or laparoscopy and normal SA. Exclusion criteria: 1) other causes of infertility such as tubal factor, male factor or unexplained infertility, 2) nausea, vomiting, orthostatic hypotension, chronic hypertension, headache, 3) sensitivity to ergot derivatives, 4) macroadenoma of pituitary gland, 5) previous use of bromocriptine or cabergoline

Age

From **19 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **188**

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 of Shiraz University of Medical Sciences

Street address

Research deputy, 7th floor, Central department of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Postal code

Approval date

2007-04-21, 1386/02/01

Ethics committee reference number

CT-86-3330

Health conditions studied

1

Description of health condition studied

Hyperprolactinemic infertile women

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

The occurrence of pregnancy

Timepoint

At 6-7 weeks of gestational age

Method of measurement

Transvaginal sonography

Secondary outcomes

1

Description

Serum prolactin level

Timepoint

4 weeks after treatment

Method of measurement

Laboratory measurment

2

Description

Treatment side effects

Timepoint

Every 4 weeks

Method of measurement

Check list

Intervention groups

1

Description

Bromocriptine 2.5 mg BID

Category

Treatment - Drugs

2

Description

Cabergoline 0.25 mg twice a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeinabiyeh Hospital
Full name of responsible person
Street address
Sarbaz Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hosein Dabbaghmanesh
Street address
Research Deputy, 7th floor, Central department of Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy 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
Iran University of Medical Sciences and Health Services
Full name of responsible person
Seyed-Mohammad Fereshtehnejad
Position
General physician, Student of MPH
Other areas of specialty/work
Street address
Medical Faculty, Iran University of Medical Sciences and Health Services, Hemmat highway
City
Tehran
Postal code
Phone
+98 21 2275 6035
Fax
Email
mohammad@stu.iums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences and Health Services
Full name of responsible person
Lida Babakhani
Position
Gynecologist
Other areas of specialty/work
Street address
Research Deputy, Central department of Shiraz University of Medical Sciences and Health Services, Zand St.
City
Shiraz
Postal code
Phone
+98 21 2230 1913
Fax
Email
dr_lida_babakhani@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences and Health Services
Full name of responsible person
Seyed-Mohammad Fereshtehnejad
Position
General physician, Student of MPH
Other areas of specialty/work
Street address
Medical Faculty, Iran University of Medical Sciences, Hemmat highway
City
Tehran
Postal code
Phone
+98 21 2275 6035
Fax
Email
mohammad@stu.iums.ac.ir
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