Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

a randomized clinical trial to compare the effect of bromocriptine-rebound method on ongoing pregnancy and live birth after Intracytoplasmic sperm injection cycles with long protocol

Protocol summary

Summary

Objectives: To assess whether Bromocriptine rebound method (BR) can improve pregnancy outcomes after ICSI cycles. Study design: prospective randomized clinical trial Method : 114 patients of infertility center of Shariati hospital since 2009-2010 Inclusion : Ovulatory women with normal serum prolactin and endocrine profile who are younger than 40 Exclusion : severe male factor based on WHO citeria The patients was randomly enrolled in two BR and Long protocol groups .BR method is similar to long protocol except administration of Bromocriptine 2.5 mg per day since day 4 of follicular phase till e7 days before gonadotropin stimulation . Primary outcome : The rate of fertilized oocytes secondary outcomes : ongoing pregnancy and live birth rates

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105016345N1**
Registration date: **2011-06-22, 1390/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-22, 1390/04/01

Registrant information

Name

Ramak Esmaeeli Azad

Name of organization / entity

Tehran University of Medical Science, Shariati hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

a randomized clinical trial to compare the effect of bromocriptine-rebound method on ongoing pregnancy and live birth after Intracytoplasmic sperm injection cycles with long protocol

Public title

The effect of Bromocriptine rebound method on Intracytoplasmic sperm injection cycles outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : normal endocrine pattern ; age younger than 40 yr ; normal basic serum prolactine concentrations ; ovulatory cycles ; Exclusion criteria : severe male factor as a cause of infertility according to the WHO criteria

Age

To **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **114**

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 Tehran University of Medical Science

Street address
Shariati Educational , Research and Healthcare Center , the beginning of Jalal Al Ahmad High way , Karegar Ave, Keshavarz BLV, Tehran, Iran

City
Tehran

Postal code

Approval date
2011-05-02, 1390/02/12

Ethics committee reference number
210/1141/90/ص

Health conditions studied

1

Description of health condition studied
IVF/ICSI

ICD-10 code
Z31.2

ICD-10 code description
In vitro fertilization

Primary outcomes

1

Description
fertilized oocyte

Timepoint
1 months after intervention

Method of measurement
embryology labratory

Secondary outcomes

1

Description
ongoing pregnancy & Live birth

Timepoint
16 weeks & 37 weeks

Method of measurement
prenatal visits

Intervention groups

1

Description
intervention : similar to long protocol except administration of Bromocriptine 2.5 mg per day since day 4 of follicular phase till 7 days before gonadotropine syimulation

Category
Treatment - Drugs

2

Description
control : long protocol In preceding cycle, OCP was administered from day 3 for a month and Buserelin (Superfact, Aventis, Frankfurt, Germany) was started 0.5 mg daily from day 21. Then, ovarian hyper stimulation was initiated with recombinant FSH (Gonal F, Serono, and Aubnne, Switzerland) in different doses according to ovarian antral follicle count in sonography on day 2 of withdrawal bleeding. Serial ultrasound examinations were used to assess ovarian response, and then gonadotropin dose adjustments were done as required. Human chorionic gonadotropin (Pregnyl, Organon, Oss, the Netherlands) 10,000 IU was administered when at least two follicles reached a mean diameter of 18 mm. Oocytes retrieval was performed 36 hours after hCG administration and oocytes were inseminated with ICSI. Evidence for fertilization was assessed approximately 18 h after insemination. Embryo transfer was performed on day 2. Luteal support with progesterone in oil (Progesterone, Aburaihan Co., Tehran, Iran) 25 mg daily IM and vaginal suppository Cyclogest was started on the day of oocytes retrieval and continued until the documentation of fetal heart activity on ultrasound. Chemical pregnancy was assessed based on Beta HCG after 14-15 days . 6 weeks later clinical pregnancy was documented based on presence of intra uterine gestational sac in trans vaginal sonography and ongoing pregnancy was determined if normal pregnancy last for more than 16 weeks .

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital ; Tehran university of medicine

Full name of responsible person
Ramak Esmaeeli Azad

Street address
the beginning of Jalal Al Ahmad High way , Karegar Ave, Keshavarz BLV

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person
Shahin Akhondzadeh (professor)

Street address
Tehran University of Medical Siences school of medicine, Pursina st. , Tehran

City
Tehran

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, Tehran 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
Tehran University of Medical Science

Full name of responsible person
Ramak Esmaeeli Azad

Position
Resident of OB & Gyn.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
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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