Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of progesterone supplementation on pregnancy rates in controlled ovarian stimulation and intrauterine insemination cycles: a randomized prospective trial

Protocol summary

Summary
The aim of this study was to evaluate the effect of vaginal progesterone as a luteal phase support on pregnancy rates in controlled ovarian hyper stimulation and intrauterine insemination cycles in couples with unexplained infertility or mild male factor infertility. This prospective randomized controlled trial was performed at the Shariati University Hospital, Tehran, Iran and private practice setting, Omid clinic and included 290 patients, who met the inclusion criteria. All the patients were undergone controlled ovarian hyper stimulation and intrauterine insemination. Men had at least two normal semen analyses before any treatment. 142 patients were randomized to start with a supported cycle and 148 patients started with an unsupported cycle. In supported cycles, the patients received vaginal progesterone once daily from the day after insemination until 12 weeks of pregnancy, and in non pregnant women for 14 days. No progesterone was given during unsupported cycles. The main outcome measures were clinical pregnancy rates per cycle.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201104266292N1**
Registration date: **2011-05-31, 1390/03/10**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2011-05-31, 1390/03/10

Registrant information
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Mahboobe Rahmani
Name of organization / entity
Tehran University of Medical Science, Shariati Hospital
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2009-10-23, 1388/08/01
Expected recruitment end date
2010-10-23, 1389/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of progesterone supplementation on pregnancy rates in controlled ovarian stimulation and intrauterine insemination cycles: a randomized prospective trial

Public title
The effect of progesterone supplementation on pregnancy rates in controlled ovarian stimulation and intrauterine insemination cycles: a randomized prospective trial
Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All women included in the study were between the age 18 and 35 years and BMI of 18-28 kg/m2, regular mense, and no PCOD (according to Rotterdam criteria), basal FSH<10 IU/L and normal serum prolactin level and normal thyroid function. All couples had been trying unsuccessfully to conceive for at least one year before being enrolled in the trial. All women had bilateral tubal patency and normal uterine cavity, confirmed by hysterosalpinography (HSG), performed a maximum of 6 months before the start the stimulation. Men had at least two semen analyses before any treatment. Normal semen analysis were defined by the threshold values of the World Health Organization criteria, ≥4% sperm had normal morphology according to the criteria of Kruger et al, or total motile sperm count ≥ 1 million following semen preparation Exclusion criteria: abnormal prolactin serum level and abnormal thyroid function test, polycystic ovary syndrome according to Rotterdam criteria, diminished ovarian reserve (basal FSH level >10 IU/mL, presence of resistant ovarian cyst (>20mm for > 1 months), hypogonadotrophic hypogonadism or any contraindications for progesterone therapy

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz Blvd, Ghods Street

City
Tehran

Postal code

Approval date
2011-05-09, 1390/02/19

Ethics committee reference number
210/1434/90/۹

Health conditions studied

1

Description of health condition studied
Female infertility, unspecified

ICD-10 code
N97.9

ICD-10 code description
inability to achieve a pregnancy

2

Description of health condition studied
Male infertility

ICD-10 code
N46

ICD-10 code description
Azoospermia NOS

Primary outcomes

1

Description
Clinical pregnancy rate

Timepoint
4 weeks after insemination

Method of measurement
Transvaginal sonography

Secondary outcomes

1

Description
Ovulation rate

Timepoint
The days 12, 14 cycles

Method of measurement
Transvaginal sonography

Intervention groups

1

Description
Intervention: application of progesterone 400 mg vaginal suppository Cyclogest once daily from the day of IUI until negative beta HCG or 12 week

Category
Treatment - Drugs

2

Description

Controi: no drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, Infertility Center

Full name of responsible person

Mahboobeh Rahmani

Street address

Gisha Brd, Amirabad Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Marzieh Aghahosseini

Street address

Gisha Brd, Amirabad Ave

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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

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, Shariati Hospital

Full name of responsible person

Mahboobeh Rahmani

Position

Resident of OB & GYN

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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