

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of luteal phase support on pregnancy rate in IUI cycles, a double blind, placebo-controlled trial

Protocol summary

Summary

The purpose of this study is to evaluate luteal phase support on pregnancy rate in IUI cycles. In this study, 260 patients with infertility who are candidate for IUI will be enrolled. For all the patients, induction of ovulation is done with Clomiphen and HMG infusion and after IUI , They are randomized into two the following groups to receive progesterone, vaginal suppository, 400 mg, or placebo vaginal suppository for 14 days. After positive B-HCG, progesterone or placebo will be continued until 8th week of clinical pregnancy confirmed by detection of fetal heart rate in TVS. Outcomes of the study are biochemical pregnancy and clinical pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011165181N2**

Registration date: **2011-03-20, 1389/12/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-03-20, 1389/12/29

Registrant information

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 9320

Email address

bhrashidi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Valiasr investigation center, Abooreihan Pharmaceutical Company

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of luteal phase support on pregnancy rate in IUI cycles, a double blind, placebo-controlled trial

Public title

Evaluation of luteal phase support on pregnancy rate in IUI cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age<35, duration of infertility less than 10 years, normal HSG and open tubes Exclusion criteria: hypothalamic amenorrhea, FSH>10

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of TUMS research administration

Street address

Tehran University of Medical Sciences-Ghods Avenue-Keshavarz Blvd-Tehran -Iran

City

Tehran

Postal code

Approval date

2010-12-22, 1389/10/01

Ethics committee reference number

11421-39-03-89

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97

ICD-10 code description

Primary outcomes

1

Description

biochemical pregnancy

Timepoint

2 weeks after treatment

Method of measurement

BHCG in serum

Secondary outcomes

1

Description

clinical pregnancy

Timepoint

8 weeks of pregnancy

Method of measurement

detect of fetal heart rate with ultrasound

Intervention groups

1

Description

Progestron suppository, 400 mg daily, for 14 days

Category

Treatment - Drugs

2

Description

placebo suppository, daily, 14 dayes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

valiasr hospital infertility clinic

Full name of responsible person

Dr Haleh Rahmanpour

Street address

Emam Khomeini hospital - Valiasr hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Valiasr reproductive health center

Full name of responsible person

Dr Haleh Rahmanpour

Street address

Emam Khomeini hospital - Valiasr hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for Research Of Tehran University of Medical Sciences

Full name of responsible person

Haleh Rahmanpoor

Street address

Building of Chancellor for Research Of Tehran University of Medical Sciences,Ghods Street ,Keshavarz Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chancellor for Research Of 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Valiasr research center

Full name of responsible person

Dr Batool Hossein Rashidi

Position

Obstetric & Gyn specialist and infertility felowship

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Dr Haleh Rahmanpour

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