

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of oral progesterone with vaginal and subcutaneous progesterone for luteal phase support on pregnancy rate of infertile patients underwent intracytoplasmic sperm injection- Embryo transfer cycles

Protocol summary

Summary

Objective: To compare pregnancy rates resulting from oral Dydrogesterone with vaginal progesterone for luteal phase support in in vitro fertilization. Design: A randomized multicenter clinical trial. Setting and conduct and participants including major eligibility criteria: This study is done in infertility clinic of Taleghani and Mahdieh Hospital, martyr Beheshti University, Tehran, Iran from April 2014 until January 2015, 200 infertile patients that are in age range of 20 -45 years old and don't have any anomaly in uterine cavity evaluation and don't have any advanced endometriosis, dense pelvic adhesion, genital TB, previous intracytoplasmic sperm injection failures which they are undergoing intra cytoplasmic sperm injection-Embryo transfer cycles are including in this study. Interventions: patients randomly have been divided into two groups or 40mg dydrogesterone (Tablet dufaston 10mg, The pharmaceutical company Abbot, Netherland)) or vaginal suppositories progesterone (suppository, 400mg , Actoverco , Great Britain) that started on oocytes recoverys day and This medication will be continued until 12 weeks of pregnancy. Main outcome measures: Clinical pregnancy rate. second outcomes measures: chemical and ongoing pregnancy and miscarriage rates, patient acceptance

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014071212494N2**
Registration date: **2014-12-08, 1393/09/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-08, 1393/09/17

Registrant information

Name

Nasrin Saharkhiz

Name of organization / entity

Infertility & Reproductive Health Research Centre of SHahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

saharkhiz.n@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Science

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral progesterone with vaginal and subcutaneous progesterone for luteal phase support on pregnancy rate of infertile patients underwent

intracytoplasmic sperm injection- Embryo transfer cycles

Public title

Effect of progesterone on pregnancy rate of assisted reproduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria; Women at age 20-45 yearsold: Underwent intracytoplasmic sperm injection-Embryo transfer(ICSI-ET)(Fresh cycle): Have normal endometrial thickness(7-12) on embryo transfer day; Don't have any observational endometrial pathology enter in to the study. Exclusion criteria; Advanced endometriosis; Dense pelvic adhesion; Genital TB; Previous intracytoplasmic sperm injection(ICSI) cycle failures.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

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**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Infertility & Reproductive Health Research Center
Ethics committee of Shahid Beheshti University of

Street address

3rd floor, Taleghani Hospital, Velenjak, Shahid
Chamran highway, Tehran

City

Tehran

Postal code

1985711151

Approval date

2014-06-25, 1393/04/04

Ethics committee reference number

308/794

Health conditions studied**1****Description of health condition studied**

Other complications associated with artificial fertilization

ICD-10 code

N98

ICD-10 code description

Noninflammatory disorders of female genital tract

Primary outcomes**1****Description**

Clinical pregnancy rate

Timepoint

Five weeks after start of intervention

Method of measurement

Transvaginal ultrasonography

Secondary outcomes**1****Description**

Patients acceptance

Timepoint

Until 12 weeks

Method of measurement

Questionare

2**Description**

Miscariage rate

Timepoint

Until 24 weeks after start of intervention

Method of measurement

History, Physical exam, Ultrasonography

3**Description**

Chemical pregnancy rate

Timepoint

Two weeks after embryo transfer

Method of measurement

Labratory kit

Intervention groups

1

Description

Intervention: Duphaston(Oral Didrogestosterone 10mg, Abbott, Netherland) 20mg , Twice daily until 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention: Subcutaneous progesterone (Prolutex, 25mg, IBSA company, Switzerland) daily injection until 12 weeks

Category

Treatment - Drugs

3

Description

Control: Vaginal suppository cyclogest,(A kind of vaginal progesterone, 400 mg, actover company,Britain)400mg twice daily until 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility & Reproductive Health Research Center
Shahid Beheshti University of Medical Science

Full name of responsible person

Marzieh Zamanian

Street address

Taleghani hospital, Velenjak, Shahid Chamran
highway, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Science

Full name of responsible person

Zahra Sadeghzade

Street address

Taleghani hospital, IVF ward, Velenjak, Shahid
Chamran highway, Tehran

City

Tehran

Grant name

معاونت پژوهشی دانشگاه علوم پزشکی شهیدبهشتی

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University
of Medical Science

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Shafayab Gostar company

Full name of responsible person

Elham Sahafi

Street address

275 plaque, after Modarres bridge, Beheshti avenue

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Shafayab Gostar company

Proportion provided by this source

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

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

Nasrin Saharkhiz

Position

Assistant professor of gynecology group

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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