

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of progesterone suppository to luteal phase support on pregnancy rates in the intrauterine insemination cycles

Protocol summary

individual

Summary

Our objective was to assess the efficacy of luteal phase support with progesterone suppository in women undergoing IUI cycles. A total of 100 couples who were undergoing IUI treatment. Ovulation induction was done for all patients. After IUI patients were randomized into two groups. The study group (n=50) received progesterone suppository and control group (n=50) received no medicine. The main outcome was the comparison of biochemical and clinical pregnancy rate, abortion rate and suppository side effects.

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progesterone suppository to luteal phase support on pregnancy rates in the intrauterine insemination cycles

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041233379N1**

Registration date: **2017-05-15, 1396/02/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-15, 1396/02/25

Registrant information

Name

Majid Rajaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3826 8887

Email address

dr.rajaee@ssu.ac.ir

Public title

The effect of progesterone on pregnancy rates in the intrauterine insemination cycles

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:normal sonograph;normal fsh , lh @AMH;without cardiac, pulmonary and renal disease;mild endometriosis;normal sperm analysais;normal HSG and exclusion criteria:more than 36 years old;previous ovarian surgery;tubal factor;severe endometriosis; Hypothalamic Amenorrhea ;Endocrine causes of infertility and amenorrhea;patients with more than 3 Follicles with 14 mm diameters;sever oligoasthenospermia

Age

To **36 years old**

Gender

Female

Phase

2-3

Groups that have been masked

No information

Recruitment status

Recruitment complete

Funding source

Sample size

Target sample size: **100**

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**

Shahid Sadoughi University of Medical Science

Street address

Shahid Bahonar sq.

City

Yazd

Postal code**Approval date**

2015-03-21, 1394/01/01

Ethics committee reference number

IR@SSU.MEDICINE.REC.1394.425

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

Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2**Description of health condition studied**

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

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

chemical pregnancy

Timepoint

16 days

Method of measurement

beta HCG>50 milli-international units per milliliter (mIU/ml)

2**Description**

clinical pregnancy

Timepoint

6 weeks

Method of measurement

gestational sac in sonography

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

abortion

Timepoint

20 weeks

Method of measurement

loss of pregnancy before 20 weeks

2**Description**

side effects

Timepoint

9 months

Method of measurement

patient

Intervention groups**1****Description**

All cycles were gently stimulated after baseline transvaginal ultrasonography with 100 mg oral tablets of clomiphene citrate daily for 5 days starting on day 3 of the menstrual cycles and a starting dose of 150 IU human menopausal gonadotropin on days 8-11 of the cycles. All patients were re-evaluated by ultrasound on day 11 for quality of the ovarian response, which was repeated every 2-3 days. The dosage of hMG was adjusted according to the ovarian response. Stimulation continued until one to three follicles reached a mean diameter of 18 mm, then 10000 IU hCG was administered and the single IUI was performed 34-36 hours later. The experimental group received progesterone vaginal Suppository 400 mg daily for luteal support . If the patient conceived, luteal support was continued through the tenth week of pregnancy. Serum hCG was obtained 2 weeks after hCG administration and intrauterine pregnancy was confirmed by detection of a gestational sac using transvaginal ultrasound 6 weeks after insemination. A clinical pregnancy was defined as the presence of a gestational sac on ultrasound or by histological examination of products of conception in patients who aborted.

Category

Treatment - Drugs

2**Description**

control group received no medicine.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Yazd Research-Clinical Center of Infertility

Full name of responsible person

Maryam Yasaei

Street address**City**

Yazd

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Individual

Full name of responsible person

Maryam Yasaei

Street address

15 Khordad Ave, Shohadaie mehrab sq.

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Individual

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**

Shahid Sadoughi University of Medical Science

Full name of responsible person

Maryam Yasaei Mehrjardi

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

Shahid Bahonar sq.

City

Yazd

Postal code**Phone**

+98 35 3724 0171

Fax**Email**

info@ssu.ac.ir

Web page address

ssu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Science

Full name of responsible person

Razieh Dehghani Firozabadi

Position

Obstetricians & gynecologist

Other areas of specialty/work**Street address**

Shahid Bahonar sq.

City

Yazd

Postal code**Phone**

+98 35 3724 0171

Fax**Email**

info@ssu.ac.ir

Web page address

ssu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Science

Full name of responsible person

Maryam Yasaei

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

Shahid Bahonar sq.

City

Yazd

Postal code**Phone**

+98 35 3724 0171

Fax**Email**

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Web page address

ssu.ac.ir

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