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

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.

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 Rajaee
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

individual

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

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

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 clomiphen 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 progestrone 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 centers

1

Recruitment center
Name of recruitment center
Yazd Research-Clinical Center of Infertility
Full name of responsible person
Maryam Yasaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Maryam Yasaei
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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
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
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Person responsible for updating data

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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