

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

comparison of the effect of cyclogess usage in vaginal or rectal form for luteal phase support on pregnancy rate of ICSI cycles and the rate of side effects and patients convenient in these two ways.

Protocol summary

Summary

The object of this study is comparison of two usage form of Cyclogest suppository, rectal or vaginal on pregnancy rate in women who are candidate for intracytoplasmic sperm injection (ICSI) and their side effects and patients convenient in these two ways. In this study 150 candidates for ICSI with long protocol enroll to study. Inclusion criteria are 20-37 years old age and first ICSI cycle. Exclusion criteria are women who have FSH>8ng/ml ,Hypothyroidy, hyperprolactinemia .On oocyte puncture day ,they allocate to two group randomly. in group 1 cyclogest suppositories administer vaginally 400 mg twice a day from oocyte puncture day for two weeks and in group 2 cyclogest suppositories administer rectally 400 mg from oocyte puncture day twice a day for two weeks and in two group 6 days after embryo transfer the progesterone of serum will be evaluated and after two weeks biochemical pregnancy will be evaluated. The side effects and patients convenient in two groups will compare to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807192568N1**
Registration date: **2011-04-20, 1390/01/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-20, 1390/01/31

Registrant information

Name

Haleh Rahmanpour

Name of organization / entity

Zanjan university of medical science

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Recruitment status

Recruitment complete

Funding source

Valiasre fertilityreaserch center,Tehran University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of cyclogess usage in vaginal or rectal form for luteal phase support on pregnancy rate of ICSI cycles and the rate of side effects and patients convenient in these two ways.

Public title

Comparison of the effect and side effects of two way of progesterone suppository use in IVF cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are : 20-37 years old wemon candidate for first ICSI cycle Exclusion criteria : FSH>8ng/ml

,Hypothyroidy,hyperprolactinemia
Age
From **20 years** old to **37 years** old
Gender
Female

Phase
2
Groups that have been masked
No information

Sample size
Target sample size: **150**
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

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Science, Medicine
faculty
Street address
Keshavarz bulvard ,ghods street ,tehran university
of medical sciences
City
tehran
Postal code
Approval date
2011-01-21, 1389/11/01
Ethics committee reference number
874

Health conditions studied

1

Description of health condition studied
artificial fertilization
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization,
unspecified

Primary outcomes

1

Description
biochemical pregnancy
Timepoint
2 weeks after drug administration
Method of measurement
blood sample - BHCG

Secondary outcomes

1

Description
Perineal itching due to Cyclogest use in vaginal or rectal
form
Timepoint
2 weeks after start of drug
Method of measurement
Ask of patients

2

Description
Vaginal discharge due to cyclogest use in vaginal and
rectal form.
Timepoint
2 weeks after drug administration
Method of measurement
Ask of patients

Intervention groups

1

Description
administration of cyclogest suppository 400 mg twice a
day in rectal form for intervention group
Category
Treatment - Drugs

2

Description
Administration of cyclogest suppository 400 mg twice a
day in vaginal form for control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasre hospital
Full name of responsible person
Dr haleh rahmanpour
Street address
Emam khomeini hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Valiasre reaserch center, Tehran university of medical sciences

Full name of responsible person

Dr Batool Hossein Rashidi

Street address

Valiasre hospital

City

Tehran

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

Yes

Title of funding source

Valiasre reaserch center, 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**

Valiasre reaserch center

Full name of responsible person

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Position

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Web page address

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