Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of oral dydrogesterone versus other forms of progesterone as a luteal cycles support in assisted reproductive technology (ART)

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is comparison of oral dydrogesterone versus other forms of progesterone as a luteal cycles support in assisted reproductive technology (ART). Total of sample size is 159 patients with ages: 20-50 years old. Inclusion criteria are patients candidate for IVF or ICSI treatment. The patients with abnormal uterus like myoma submucosal, endometrial adhesion and lack of fertilization will be excluded. Patients are randomly divided into three groups with table of random numbers by computer. Patients and Assessor of study do not know about type of drug. This study is trial phaseII. First group receives 10 mg oral dose of Dydrogesterone tablet Three times a day until twelve weeks of pregnancy. Second group receives 400 mg of progesterone vaginal suppository twice a day until twelve weeks of pregnancy. Third group receives 50 mg of intramuscular progesterone twice a day until twelve weeks of pregnancy. Information of patients such as age and BMI, cause of infertility, duration of infertility, the type of ovulation induction (short agonists and long agonist and antagonist), assisted reproductive technique (IVF and ICSI), methods for luteal phase support (intramuscular progesterone and progesterone vaginal suppository and dydrogesterone tablet), endometrial thickness of embryo transferred, grade and the number of transferred embryo cells and amount of live births will be recorded in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010825902N1**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name
Maryam Sadat Ejtahed
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3222 2922
Email address
ejtahed.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-18, 1394/07/26

Expected recruitment end date

2016-03-16, 1394/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral dydrogesterone versus other forms of progesterone as a luteal cycles support in assisted reproductive technology (ART)

Public title

The effect of dydrogesterone and various forms of progesterone in support of artificial reproduction

techniques

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients candidate for in vitro fertilization (IVF) or intracytoplasmic cytoplasmic sperm injection (ICSI); Having a normal uterus. Exclusion Criteria: Abnormal uterus such as submucosal myoma and endometrial adhesions; Sensitivity to progesterone; Lack of fertilization; Having a systemic disease.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Initially, all patients are placed under transvaginal ultrasound then appropriate drugs is prescribed to patient for stimulation of ovulation based on patient cycle (short agonists and long agonist and antagonist). Transvaginal ultrasound is repeated once every five days. HCG will be prescribed when at least three follicles reach a diameter of over 18 mm. Ovum retrieval is done by transvaginal 36 hours after the injection HCG. In all patients will be prescribed dydrogesterone and progesterone for luteal phase support since ovum retrieval based on grouping patients. Embryo in the third to fifth day after ovum retrieval will be transferred to each patient with the number and grade of different. The criterion standard for pregnancy test is defined by a serum positive HCG on twelfth day after the fetal transfer and viewing the fetal heart on ultrasound.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2015-10-17, 1394/07/25

Ethics committee reference number

IR.AJUMS.AC.1394.417

Health conditions studied

1

Description of health condition studied

Artificial fertilization

ICD-10 code

N98.2

ICD-10 code description

Complications of attempted introduction of fertilized ovum following in vitro fertilization

Primary outcomes

1

Description

Pregnancy

Timepoint

Once a week after embryo transfer into the patient

Method of measurement

The blood hCG test

2

Description

Preterm delivery

Timepoint

Every two weeks from the twentieth week of pregnancy

Method of measurement

Patient appointments and record uterine contractions

3

Description

Amount of live birth

Timepoint

Every two weeks from twenty-eighth week of pregnancy

Method of measurement

Patient appointments and record baby's birth

4

Description

Grade and the number of transferred embryo cells

Timepoint

Immediately before embryo transfer into the patient

Method of measurement

By using microscope

Secondary outcomes

1

Description
Perineal irritation caused by progesterone vaginal suppository
Timepoint
Every two weeks during treatment period
Method of measurement
Verbal questionnaire and the patient's response

Intervention groups

1

Description
Intervention group 1: Prescription oral dose of 10 mg of dydrogesterone, Three times a day, since ovum retrieval until the twelfth week of pregnancy.
Category
Treatment - Drugs

2

Description
Intervention group 2: Prescription 400 mg of progesterone vaginal suppository, twice a day, since ovum retrieval until the twelfth week of pregnancy.
Category
Treatment - Drugs

3

Description
Control group: Prescription 50 mg of intramuscular progesterone, twice a day, since ovum retrieval until the twelfth week of pregnancy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Treatment Center of University ACECR of Khuzestan
Full name of responsible person
Najmieh Saadati
Street address
Infertility Treatment Center of University ACECR of Khuzestan, Pardis Blv, Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki
Street address
Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz
City
Ahvaz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor For Research Of Ahvaz Jundishapur 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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Maryam Sadat Ejtahed
Position
Resident of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz
City
Ahvaz
Postal code
Phone
+98 61 3222 2922
Fax
Email
dr.maryamejtahed@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person

Mahvash Zargar

Position

Fellowship of Infertility of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

dr.zargar199@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Nazari

Position

Nurse Anesthesia

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

-

Phone

00

Fax

-

Email

s.nz1990@yahoo.com

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