

# 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 phasell. 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 Jundishapur 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

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## 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**

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**Full name of responsible person**

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**Position**

Nurse Anesthesia

**Other areas of specialty/work**

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s.nz1990@yahoo.com

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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*