# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of the effect of oral progesterone and vaginal progesterone on luteal phase support using available drugs in IVF/ICSI candidates

## Protocol summary

**Study aim**
Comparison of the effect of oral progesterone and vaginal progesterone on luteal phase support using available drugs in IVF/ICSI candidates

**Design**
160 participant are divided randomly in to two groups of 80 who are administered oral or vaginal progesterone as an luteal phase support. The randomization is performed using random allocation rule.

**Settings and conduct**
the study will be hold in IVF clinic in Ayatollah mousavi hospital. each participant is administered with either vaginal or oral progesterone as a luteal phase support and the pregnancy out come is compared between two group.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1. IVF/ICSI candidates 2. age between 18 to 40 years old 3. available informed written consent exclusion criteria: 1. history of drug reaction to drugs used in this study 2. endometriosis 3. Partner azospermia 4. Uterine anatomical anomaly 5. endocrine or metabaolic disorder 6. 2 or more unsuccessful IVF or FET 7. repetitive spontaneous abortion

**Intervention groups**
Vaginal or oral progesterone is administered in two different groups as an luteal phase support

**Main outcome variables**
successful pregnancy Unsuccessful pregnancy ( abortion or preterm labor)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20211101052938N1**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **prospective**
Last update: **2022-10-12, 1401/07/20**
Update count: **1**

**Registration date**
2021-11-14, 1400/08/23

**Registrant information**

**Name**
Nazli Ghamari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 24 3313 0001

**Email address**
nazlighamari@zums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-12-02, 1400/09/11

**Expected recruitment end date**
2022-03-31, 1401/01/11

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the effect of oral progesterone and vaginal progesterone on luteal phase support using available drugs in IVF/ICSI candidates

**Public title**
Comparison of the effect of oral progesterone and vaginal progesterone on luteal phase support

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
IVF/ICSI candidate with history of infertility age between 18 to 40 years old have an informed consent to participate in the study
**Exclusion criteria:**
drug reaction history to one of the drugs used in this study endocrine or metabolic disorders endometriosis Azospermia of partner uterine anatomic anomaly history of 2 or more unsuccessful IVF or FET history of repetitive spontaneous abortion

**Age**
From **18 years** old to **40 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **160**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
For randomized categorization of the participants we use random allocation rule. 160 participants are divided randomly in to two even groups of 80; case group and control group. The written name of participants are put in the accordant bowl randomly and without replacement and subsequent random sequence will be made.

**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**
Ethics committe of Zanjan university of medical sciences

**Street address**
Azadi Blv, Zanjan university of medical sciences, Postal code: 4515613191

**City**
Zanjan

**Province**
Zanjan

**Postal code**
4515613191

**Approval date**
2021-10-30, 1400/08/08

**Ethics committee reference number**
Ir.Zums.REC.1400.346

## Health conditions studied

**1**

**Description of health condition studied**
In vitro fertilization

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Percent of successful pregnancy following in vitro fertilization

**Timepoint**
Evaluating the outcome of pregnancies at the end of the study

**Method of measurement**
Recording the successful and unsuccessful pregnancy

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: in this group 400 mg vaginal progesterone (Fertigest 400 mg vaginal of Aburaihan Pharmaceutical Co)is prescribed for luteal phase support.

**Category**
Treatment - Drugs

**2**

**Description**
Control group: In this group Dofamed 10 mg (Atipharmed Pharmaceutical Company) is prescribed orally three times a day for luteal phase support.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
IVF clinic of Ayatollah mousvi hospital of Zanjan

**Full name of responsible person**
Nazli Ghamari

**Street address**
IVF clinic, Ayatollah Mousavi Hospital, Gavazang Road, Above Shahid Sabouti Boulevard, Zanjan, Iran.

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Mousavihospital@zums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Alireza Ganji
**Street address**
Zanjan University of Medical Sciences , Dr.Sobouti Blvd. Zanjan,Iran
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aganji@zums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zanjan University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Nazli Ghamari
**Position**
Senior resident of obstetric and gynaecology
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
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## Person responsible for scientific inquiries

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Medical Resident
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Not applicable