

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women referred to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study

#### Protocol summary

##### Study aim

Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support

##### Design

classification into two groups (IM group, Crinone group) 3 days before FET, frozen embryo transfer, evaluation of pregnancy outcomes

##### Settings and conduct

All infertile participants referred to the infertility center after obtaining informed consent involve the study and receive hormone therapy for preparing the endometrium for embryo transfer and subsequent receive luteal phase support. All patients are randomly divided into two groups before starting treatment: Group 1: Administration of 100 mg of progesterone as IM (two ampoules of 50 mg) from 3 days before embryo transfer until pregnancy test Group 2: Administration of 8% crinone gel (90 mg once daily) from 3 days before embryo transfer until pregnancy test In all patients, 2-3 good quality embryos are transferred 96 hours after the start of progesterone administration. Serum progesterone levels are measured 1 hour before embryo transfer and the pregnancy outcomes in each patient are assessed and the relationship between serum progesterone levels and these outcomes is assessed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Artificial endometrial preparing 18-37 years. ICSI/IVF cycles Having 2-3 high quality embryos Patients with normal uterine cavity Exclusion criteria: Patients with uterine problems Patients with a history of recurrent miscarriage RIF patients Age over 37 years Patients with grade 3 or 4 endometriosis Poor Embryo

quality Ectopic pregnancy Patients with endometrial thickness less than 7 mm after hormone therapy

##### Intervention groups

Group1: women receiving progesterone IM Group2: women receiving vaginal progesterone ( crinone gel 8%)

##### Main outcome variables

Biochemical pregnancy, clinical pregnancy, ongoing pregnancy, abortion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200905048630N2**

Registration date: **2021-08-22, 1400/05/31**

Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**

Update count: **0**

##### Registration date

2021-08-22, 1400/05/31

##### Registrant information

##### Name

Ensieh Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3333 0755

##### Email address

salehiensieh@hums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2021-09-21, 1400/06/30

### Expected recruitment end date

2021-11-21, 1400/08/30

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women refereed to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study

## Public title

Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women refereed to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

ICS/FET cycles Having 2-3 high quality embryo Patients with normal uterine cavity Infertile women between 18-37 years Artificial Endometrial preparing

### Exclusion criteria:

RIF patients Aged over 37 years Patients with a history of recurrent miscarriage, implantation problem Patients with uterine abnormality like Fibroma, uterine anatomical problems, Polyp, intramural Myoma greater than 4 cm, salpingitis Patients with grade 3 or 4 endometriosis Body mass index higher than 30 kg / m2 Patients using two types of progesterone to support the luteal phase Patients with blastocyst transfer (fifth day embryo) Ectopic pregnancy Patients with endometrial thickness less than 7 mm after hormone therapy Poor quality embryo

## Age

From **18 years** old to **37 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

N/A

## Randomization description

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

Eligible patients (including 100 patients) are randomly assigned by a statistical expert using a simple randomization method. In this method, the Random function between the Excell program is used to generate a random number between 1 and 2. This is repeated 100 times and thus a random sequence is obtained.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

##### Street address

Imam Hossein Boulevard

##### City

Bandar abbas

##### Province

Hormozgan

##### Postal code

7919693116

#### Approval date

2021-08-10, 1400/05/19

#### Ethics committee reference number

IR.HUMS.REC.1400.192

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Biochemical pregnancy

#### Timepoint

14 days after FET

#### Method of measurement

beta serum level evaluation

## 2

### **Description**

Clinical pregnancy

### **Timepoint**

6 week after FET

### **Method of measurement**

Sonography

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: receiving progesterone as IM

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: receiving vaginal progesterone( crinone gel 8%)

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Infertility center affiliated to Hormozgan University of Medical Sciences

##### **Full name of responsible person**

Dr.Maryam Azizi kuteanaee

##### **Street address**

Parastar Street

##### **City**

Bandar Abbas

##### **Province**

Hormozgan

##### **Postal code**

7916613885

##### **Phone**

+98 76 3333 0755

##### **Email**

maryamazizikut86@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Bandare-abbas University of Medical Sciences

##### **Full name of responsible person**

Dr.taymoor Aghamolaei

#### **Street address**

Imam Hossein Boulevard

#### **City**

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#### **Postal code**

7919693116

#### **Phone**

+98 76 3371 0393

#### **Email**

research@hums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

##### **Full name of responsible person**

Dr. Maryam Azizi kuteanaee

##### **Position**

Associate professor

##### **Latest degree**

Subspecialist

##### **Other areas of specialty/work**

Gynecology and Obstetrics

##### **Street address**

Parastar Street

##### **City**

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##### **Province**

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##### **Postal code**

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Azizi Kutenae

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Associate Professor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr. Ensieh Salehi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

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**Phone**

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**Email**

salehiensieh@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The data will be presented in the article after analysis

**When the data will become available and for how long**

2022

**To whom data/document is available**

Academic researchers and Gynecologist

**Under which criteria data/document could be used**

Clinical application in patients undergoing ICSI/FET

**From where data/document is obtainable**

corresponding author

**What processes are involved for a request to access data/document**

E-mail to corresponding author

**Comments**