

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### assessment of the best luteal phase support (comparison of four protocols) for patients undergoing frozen-thawed embryo transfer in artificial cycle.

#### Protocol summary

##### Summary

overall objective of the best luteal phase support upon pregnancy outcome in frozen –thawed embryo transfer cycle dedicated objectives : 1-survey effect of didrogesteron in comparison by cyclogest upon clinical pregnancy rate in frozen thawed embryo transfer cycle 2- survey effect of didrogesteron in comparison by cyclogest upon ongoing pregnancy rate in frozen thawed embryo transfer cycle 3- survey effect of didrogesteron in comparison by cyclogest upon abortion rate in frozen –thawed embryo transfer cycle 4- survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon clinical pregnancy rate in frozen –thawed embryo transfer cycle 5- survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon ongoing pregnancy rate in frozen –thawed embryo transfer cycle 6-survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon abortion rate in frozen –thawed embryo transfer cycle 7- survey effect of didrogesteron with HCG in comparison by cyclogest upon clinical pregnancy rate in frozen –thawed embryo transfer cycle 8-survey effect of didrogesteron with HCG in comparison by cyclogest upon ongoing pregnancy rate in frozen –thawed embryo transfer cycle 9- survey effect of didrogesteron with HCG in comparison by cyclogest upon abortion rate in frozen thawed embryo transfer cycle inclusion criteria: 1-unexplained infertility 2- tubal factor 3-mild male factor 4-POF 5-sub fertility in pco field 6-average age between 20-40 7-normal uterine cavity exclusion criteria: 1-women over 40 year 2- endometriosis stage III ,IV 3-Hydro salpinx 4- severe male factor 5-ab normal uterine cavity 6-failed embryo transfer cycle  $\geq 3$  methods: According to previous studies and consult with statistics 400 patients were entered to our study.patients who were scheduled for IVF in infertility clinic of mother and child hospital,and Dena hospital of Shiraz city were assessed for having inclusion

criteria,patients that were 20-40 y with normal uterine cavity and special infertility cause were included and patients that had more than 40 y with abnormal uterine cavity and more or equal 3 unsuccessful embryo transfer cycle were excluded . After entrance to stimulation cycles ,in third day of past ovum pick up,embryos were assessed for quality and counts of blastomers.If number of blastomers were more than or equal 8 with fragmentation rate less than 20%,embryo was freezes as Top quality embryo with vitrification method in cleavage stage.The patients who had Top quality freeze embryo were admitted in next cycle for preparation endometrium. Estradiol was started from second day of menstrual cycle , progesterone ampule 100 mg/d for three days was prescribed after getting adequate endometrial thickness. Number of embryo for transfer was determined according to mother age. after taking testimonial form study,patients randomized and divided to four groups for receiving luteal phase support. - First group:patients who received cyclogest vaginal suppository 400 mg twice a day. - Second group: patients who received didrogesteron oral tablet 10 mg twice a day. - Third group: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp Dipherelin 0.1mg in days of embryo transfer,3 day,6 day . - Fourth group: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp HCG 1500u in days of embryo transfer,3 day,6 day - HCG Test was done 16 days after embryo transfer.if the test was positive ,trans vaginal ultra sound was done 6 week and 12 week later for determining clinical pregnancy rate and ongoing pregnancy rate.Meanwhile luteal phase support was continued till 12 week gestation. - Main outcome were consist of clinical pregnancy rate ,ongoing pregnancy rate, abortion rate that was recorded for 4 groups and after statistical analysis were compared for assessing best luteal phase support in frozen-thaw embryo transfer cycle.

## General information

### Acronym

### IRCT registration information

IRCT registration number: **IRCT2014082510210N3**

Registration date: **2015-02-14, 1393/11/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

### Registration date

2015-02-14, 1393/11/25

### Registrant information

#### Name

Afsun Zarei

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 71 1233 2365

#### Email address

zareia@sums.ac.ir

### Recruitment status

**Recruitment complete**

### Funding source

Shiraz University of Medical Sciences

### Expected recruitment start date

2014-12-16, 1393/09/25

### Expected recruitment end date

2015-06-15, 1394/03/25

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

### Scientific title

assessment of the best luteal phase support (comparison of four protocols) for patients undergoing frozen-thawed embryo transfer in artificial cycle.

### Public title

Effect of four treatment protocols upon pregnancy outcome in frozen-thawed embryo transfer cycle.

### Purpose

Treatment

### Inclusion/Exclusion criteria

inclusion criteria: unexplained infertility : tubal factor: mild male factor : POF : sub fertility in pco field : average age between 20-40: normal uterine cavity exclusion criteria: women over 40 year: endometriosis stage III ,IV: Hydro salpinx : severe male factor: ab normal uterine cavity : failed embryo transfer cycle  $\geq 3$

### Age

From **20 years** old to **40 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **280**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical Science Researching, Shiraz University of Medical Science

##### Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

##### City

Shiraz

##### Postal code

##### Approval date

2014-12-14, 1393/09/23

##### Ethics committee reference number

ct-p-9384-8114

## Health conditions studied

### 1

#### Description of health condition studied

luteal phase

#### ICD-10 code

N94.8

#### ICD-10 code description

Other specified conditions associated with female genital organs and menstrual cycle

## Primary outcomes

### 1

#### Description

Clinical pregnancy rate

#### Timepoint

6 week gestation

#### Method of measurement

vaginal sonography trans

## Secondary outcomes

### 1

#### Description

ongoing pregnancy rate, Abortion rate

#### Timepoint

12 week gestation

#### Method of measurement

vaginal sonography trans

## Intervention groups

### 1

#### Description

control group : received cyclogest vaginal suppository twice a day for luteal phase support

#### Category

Treatment - Drugs

### 2

#### Description

intervention group 1: patients who received didrogesteron oral tablet 10mg twice a day.

#### Category

Treatment - Drugs

### 3

#### Description

intervention group2: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp Dipherelin 0.1mg in days of embryo transfer,(3 day,6 day )

#### Category

Treatment - Drugs

### 4

#### Description

intervention group3: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp HCG 1500u in days of embryo transfer,(3 day,6 day)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mother & Child hospital

##### Full name of responsible person

Parastoo soheil

##### Street address

Shiraz University of Medical Sciences, Zand Street,

Shiraz

#### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Basir Hashemi

##### Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

##### City

Shiraz

#### 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 Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr parastoo soheil

##### Position

Fellowship of Obstetrics & GYN, Infertility

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*