

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of efficacy of GM-CSF in embryo culture for freezed embryos in embryo development and pregnancy outcomes

#### Protocol summary

##### Summary

In this double blind controlled trial study,80 women that had 4 good quality embryo after thawing in Avicenna center were included.these patients was divided to two group by randomization. we will study beta-HCG level,implantation and clinical pregnancy rates ,abortion under 12 weeks,multiple pregnancy , embryo qualities before ET and blastocyst outgrowth in 2 groups.In intervention group embryos after thawing will cultured in embryo culture whit GM-CSF (Embryogen) and in another group embryos will cultured in G2 medium(Vitrolife) without GM-CSF.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014021611430N4**  
Registration date: **2014-03-17, 1392/12/26**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-17, 1392/12/26

##### Registrant information

###### Name

Simin Zafardoust

###### Name of organization / entity

Jahad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2264 4701

###### Email address

s.zafardoost@avicenna.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Infertility and recurrent abortion treatment center of avicenna

##### Expected recruitment start date

2014-03-11, 1392/12/20

##### Expected recruitment end date

2014-07-21, 1393/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy of GM-CSF in embryo culture for freezed embryos in embryo development and pregnancy outcomes

##### Public title

Efficacy of embryo culture on freezed embryos and pregnancy outcome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1)Couples that undergoing treatment whit own gametes 2)women under 40 ears old 3)Women whit at least 4 good quality embryo after thawing(grade A) 4)Women that did not have more than 1 previous embryo transfer Exclusion criteria: 1)Cycles whit no PGD(Preimplantation genetic diagnosis) 2)Women whit no uterine anatomic disorder or hydrosalpinx

##### Age

To **42 years** old

##### Gender

Female

##### Phase

4

#### Groups that have been masked

No information

### Sample size

Target sample size: 80

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research center of Avicenna

##### Street address

97 no.Yakhchal street, Shariati Street.

##### City

Tehran

##### Postal code

19419113194

#### Approval date

2014-01-14, 1392/10/24

#### Ethics committee reference number

92-037

## Health conditions studied

### 1

#### Description of health condition studied

In vitro fertilization

#### ICD-10 code

Z31.2

#### ICD-10 code description

In vitro fertilization

## Primary outcomes

### 1

#### Description

Development of embryos to blastocysts

#### Timepoint

5 days after intervention

#### Method of measurement

Microscopic evaluation of embryos

### 2

#### Description

Implantation rate

#### Timepoint

5 weeks after intervention

#### Method of measurement

Vaginal ultrasonography

### 3

#### Description

Clinical pregnancy rate

#### Timepoint

6 weeks after intervention

#### Method of measurement

Vaginal ultrasonography

## Secondary outcomes

### 1

#### Description

Quality of embryos

#### Timepoint

5 days after intervention

#### Method of measurement

Microscopic evaluation of embryos

### 2

#### Description

Beta HCG level

#### Timepoint

19 days after intervention

#### Method of measurement

Blood sample evaluation

### 3

#### Description

Evaluation of abortion under 12 weeks

#### Timepoint

12 weeks after intervention

#### Method of measurement

History of patient

### 4

#### Description

Multiple pregnancy

#### Timepoint

5 weeks after intervention

#### Method of measurement

Vaginal ultrasonography

## Intervention groups

### 1

#### Description

In intervention group , embryos after thawing will cultured in medium with growth factor and in control group they will cultured in medium without growth factor. IN two groups will evaluate Blastocyst

development and embryo quality.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Infertility and recurrent abortion treatment center of Avicenna

**Full name of responsible person**

Dr Sadeghi Mohammd Mehdi

**Street address**

97 no.Yakhchal street, Shariati Street.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Infertility and recurrent abortion treatment center of Avicenna

**Full name of responsible person**

Mohammad Mehdi Akhondi

**Street address**

97 no.Yakhchal street, Shariati Street.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Infertility and recurrent abortion treatment center of Avicenna

**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**

Infertility and recurrent abortion of Avicenna

**Full name of responsible person**

Zafardoust Simin

**Position**

Obsteterics and Gynecologist- Fellowship of infertility

**Other areas of specialty/work****Street address**

97 no.Yakhchal street, Shariati Street.

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Sadeghi@avicenna.ac.ir s.zafardoost@avicenna.ac.ir

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Infertility and recurrent abortion treatment center of Avicenna

**Full name of responsible person**

Dr Sadeghi Mohammad Reza

**Position**

Embryologist - PHD

**Other areas of specialty/work****Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Infertility and recurrent abortion treatment center of Avicenna

**Full name of responsible person**

Dr Zafardoost Simin

**Position**

Obstetrics and Gynecologist-Fellowship of infertility

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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*