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
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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

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr Sadeghi Mohammad Reza

Position
Embryologist - PHD

Other areas of specialty/work

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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

Other areas of specialty/work

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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