

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of sequential day3/ day5 embryo transfer on Improvement of pregnancy rate in patients with repeated implantation failure

Protocol summary

Study aim

Evaluation of the effect of sequential embryo transfer on pregnancy outcome in repeated implantation failure (RIF) patients

Design

The study was designed as two armed randomized clinical trial with 100 patients in each group of patients with RIF. Stratified block will perform using site: <https://www.sealedenvelope.com> based on age and number of failures.

Settings and conduct

The trial will be performed in two infertility treatment center (Avicenna fertility clinic and Bahman hospital). Volunteer patients will be enrolled to the study after evaluation of inclusion and exclusion criteria. After ovarian stimulation , follicles size will be determined in 9th days of menstruation cycle using ultrasound, then HCG will be injected and the ovarian puncture procedure will be implemented. Then patients will be randomly allocated in two groups with Stratified Block Randomization method using www.sealedenvelope.com site as Intervention group (Sequential Embryo transfer) and Control Group (one step embryo transfer). This trial is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : History of at least 2 implantation failure in assisted reproduction techniques ,
Age<40,Normal karyotype,Normal Endometrium,at least 3 good quality embryo in embryology laboratory,
Exclusion Criteria : Hetero-zygote thrombophilia at least in 2 gene,Hydrosalpinx, severe male factor infertility

Intervention groups

Intervention group: Sequential embryo transfer will be done in days 3 and then 5 after fertilization
Control group: Common embryo transfer will be done in day 5 after fertilization

Main outcome variables

Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200421047152N1**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Arash Mohazzab

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2351 9630

Email address

amohazzab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of sequential day3/ day5 embryo transfer on Improvement of pregnancy rate in patients with repeated implantation failure

Public title
Sequential embryo transfer trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with history of implantation failure more than two times Age<40 At least 3 good quality embryo formation in embryology lab Normal endometrium Normal karyo-type
Exclusion criteria:
 Hetero zygote thrombophilia panel > 2 Hydrop-salpinx Severe male factor Infertility

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be Stratified block randomization based on age and number of previous treatment failure. Patients will be categorized into quadri-cell blocks based on age (higher and lower than 30) and also number of previously failed treatment (higher and lower than 5) , then they will be allocated randomly in two groups of the trial using the <https://www.sealedenvelope.com> site's software.

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

Ethical committee of Avicenna Reserch Institute,ACECR affiliated research institute in biotechnology

Street address
Daneshjou Blvrd. Evin. Chamran Exp.way

City
Tehran

Province
Tehran

Postal code
1985743413

Approval date
2020-05-12, 1399/02/23

Ethics committee reference number
IR.ACECR.AVICENNA.REC.1399.001

Health conditions studied

1

Description of health condition studied

Recurrent implantation failure

ICD-10 code

N98.2

ICD-10 code description

Complications of attempted introduction of fertilized ovum following in vitro fertilization

Primary outcomes

1

Description

Clinical Pregnancy

Timepoint

3rd- 4th week after embryo transfer

Method of measurement

Trans-vaginal ultrasound

Secondary outcomes

1

Description

Chemical Pregnancy

Timepoint

two or three weeks after Embryo transfer

Method of measurement

Serum Beta HCG

Intervention groups

1

Description

Intervention group: Embryo transfer will be done in two steps in this group.A good quality morola phase embryo will be transfered in 3rd day after fertilization. In the next step a good quality blastocyst phase embryo will be transfered in the 5th day

Category

Treatment - Surgery

2

Description

Control group: Two good quality blastocyst phase embryos will be transferred in day 5th after fertilization

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Fertility Clinic

Full name of responsible person

Soheila Arefi

Street address

Yakhchal Junction , Shariati street

City

Tehran

Province

Tehran

Postal code

1941913114

Phone

+98 21 23519

Email

soheilaarefi@yahoo.com

2

Recruitment center

Name of recruitment center

Bahman Hospital

Full name of responsible person

Sohelia Arefi

Street address

North Iran Zamin Street , Shahrak-Gharb

City

Tehran

Province

Tehran

Postal code

1465795481

Phone

+98 21 8857 5901

Email

soheilaarefi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Mohammad Reza Sadeghi

Street address

Daneshjou Blvd, Evin

City

Tehran

Province

Tehran

Postal code

1936773493

Phone

+98 21 2243 2020

Email

Sadeghi@avicenna.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Avicenna Research Institute

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

Iranian academic center for education culture and research

Full name of responsible person

Professor Soheila Arefi

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Inferility

Street address

Yakhchal Junction , Shariati

City

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Province

Tehran

Postal code

1941913114

Phone

+98 21 23519

Email

soheilaarefi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

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Position

Associated Professor

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Postal code

1941913114

Phone

+98 21 23519

Email

soheilaarefi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Arash Mohazzab

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Yakhchal Junction, Shariati street

City

Tehran

Province

Tehran

Postal code

1941913114

Phone

+98 21 2351 9630

Fax

Email

amohazzab@yahoo.com

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Informed consent in which was approved by ethical committee will be available for medical researchers.

When the data will become available and for how long

After patients recruitment

To whom data/document is available

medical researchers

Under which criteria data/document could be used

Trial design

From where data/document is obtainable

Professor Soheila Arefi Dr. Arash Mohazzab

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

Email request

Comments