

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of sperm selection using sperm bounded to zona pellusida of immature oocyte and sperm selection by current methods on embryo morphokinitic and clinical fertility outcomes in infertile couples

Protocol summary

Study aim

Determination of embryocytokinetic and outcomes of intracytoplasmic sperm injection using sperms bound to the zona pellucida of immature oocytes

Design

This study is designed as a clinical trials with parallel control and intervention groups. Sperms are derived from main sperm sample that gathered from male patient. Blindness has not been performed and study has been performed on 50 infertile couples.

Settings and conduct

location of this research is the Research and Clinical Center for Infertility, faculty of medicine, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: less than 40 years old; at least six MII oocytes and one meta phase I oocyte retrieved; Semen samples with sperm concentration more than 5 million motile spermatozoa/ml. Non-inclusion criteria: Non ejaculated spermatozoa (testicular or epididymal sperm retrieval).

Intervention groups

Each patient's oocyte are divided into control and target groups Intervention group 1: intracytoplasmic sperm injection usingsperm bound to the zona pellucida of immature oocytes control group :conventional intracytoplasmic sperm injection

Main outcome variables

Rate of implantation; Clinical pregnancy rate

General information

Reason for update

1- The reason for changing the start time of the study was that we had to start work after the production of IRCT approval. 2- Remove of one of the secondary

outcome named integration of embryo zona pellucida was that the embryos would not be out of the incubator for longer than necessary. 3- Primary and secondary outcomes updated. 4-The target sample size was updated (after statistical study, the decision was made to change).

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048021N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **1**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Mahin Izadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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mizadi890112@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-26, 1399/12/08

Expected recruitment end date

2022-02-28, 1400/12/09

Actual recruitment start date

2020-10-28, 1399/08/07

Actual recruitment end date

2022-01-05, 1400/10/15

Trial completion date

2022-04-23, 1401/02/03

Scientific title

Comparison of the effects of sperm selection using sperm bounded to zona pellusida of immature oocyte and sperm selection by current methods on embryo morphokinitic and clinical fertility outcomes in infertile couples

Public title

Effects of sperm selection by zona pellucida binding method on fertility outcomes and embryo morphokinitics

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 40 years old At least six MII oocytes and one metaphase I oocyte retrieved Spouse semen samples with sperm concentration more than 5×10^6 motile spermatozoa

Exclusion criteria:

Non ejaculated spermatozoa (testicular or epididymal sperm retrieval) (for example: Azoospermia and cryptoazoospermia) cases in which the sperm cells were not bound to the zona pellucida for any reason Women with polycystic ovary syndrome

Age

To **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation is used for randomization. In this way, one of the two completely identical balls with numbers 1 or 2 in a lottery container is randomly selected and then with the arrival of ball 1, the sample is allocated to the control group and the ball 2 is allocated to the intervention group.

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**

Ethics committee of Yazd University of Medical Sciences

Street address

Yazd Reproductive Sciences Research Institute; Bouali street; Safaieh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2019-09-15, 1398/06/24

Ethics committee reference number

IR.SSU.RSI.REC.1398.022

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes**1****Description**

Rate of clinical pregnancy

Timepoint

Rate of clinical pregnancy is evaluated 6 weeks after assisted reproductive technique.

Method of measurement

Clinical pregnancy is measured through the recording of heart beat by ultrasonography.

Secondary outcomes**1****Description**

Fertilization rate

Timepoint

Sixteen to 20 hours after performing of assisted reproductive technique.

Method of measurement

Appearance of pronucleus by binocular loop observation

2**Description**

Embryo quality

Timepoint

Three days after performing of assisted reproductive technique

Method of measurement

Total number of normal blastomer and percent of fragmented blastomer in defined time points using Time-Laps system.

3

Description

Rate of chemical pregnancy

Timepoint

Two weeks after performing of assisted reproductive technique

Method of measurement

Measurement of serum Beta-Human Chorionic Gonadotropin

4

Description

time lapse parameters

Timepoint

After intracytoplasmic injection of sperm (time 0), the following time points are measured: Time of disappearance of pronucleus in zygote (tPNF), Zygote divides into two cells (T2), three cells (T3), four cells (T4), five cells (T5), six cells (T6), seven cells (T7) and eight cells (T8).

Method of measurement

Analyzing and measurement using EmbryoViewerTM software

5

Description

Rate of implantation

Timepoint

The rate of implantation is assessed 1 week to 10 days after the assisted reproduction technique.

Method of measurement

Rate of implantation is determined by observation of gestational sac through the vaginal sonography.

Intervention groups

1

Description

Intervention group: intracytoplasmic sperm injection using the zonapellucida-bound sperm to immature oocyte.

Category

Treatment - Other

2

Description

Control group: conventional intracytoplasmic sperm injection

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Research Center; Shahid Sadoughi University of Medical Sciences; Yazd

Full name of responsible person

Abbas Aflatoonian

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Bouali street; Safaieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Ali Khalili

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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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

Yes - There is 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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data that will be shared with other researchers after removing the identification data of participants: 1- Fertilization rate by examining the formation of pronucleus in the egg cell. 2- Assessment of embryo quality and morphokinetics by the time lapse system and calculating the time related to the process of cell division of the embryo. 3- Chemical and clinical pregnancies one week and seven weeks, respectively, after embryo transfer.

When the data will become available and for how long

Up to one year after publication the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Again with the consent of the participants and the researcher responsible for the project

From where data/document is obtainable

Mohammad Ali Khalili 09133570876

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

Send a request via email to the responsible researcher

Comments