

# 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)

##### Phone

+98 35 3720 8965

##### Email address

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  $5 \times 10^6$  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

##### Street address

Bouali street; Safaieh

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877391

##### Phone

+98 35 3824 8119

##### Email

mizadi890112@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Bouali Street; Safaieh

##### City

Yazd

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

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**Full name of responsible person**

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**Position**

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**Latest degree**

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

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**Full name of responsible person**

Mahin Izadi

**Position**

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**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

Khalili59@hotmail.com

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

Send a request via email to the responsible researcher

## Comments