

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of clinical outcomes of infertile individuals candidate for ICSI using capillary-cumulus oophorus model versus routine method: A randomized single-blind controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of clinical outcomes of infertile individuals candidate for ICSI using capillary-cumulus oophorus model versus routine method

##### Design

The researcher fully explains the study design for the couples candidate for ICSI (N=40). If couples consent, they will be included in the study. On ICSI day, half of the patient's wife's oocytes will be selected by sperm that has passed through the cumulus oophorus layer and injected into the oocyte. While the other half of the oocytes, sperm will be selected only on the basis of morphology and viability and injected into the oocyte. The next day, the embryologist will evaluate the fertilization rate, the quality of the embryo on day two and day three. Finally, the best embryo is selected and transferred to the uterus.

##### Settings and conduct

This study will be conducted at Infertility Center. Data analysis and interpretation at Royan Institute for Biotechnology. The embryologist is blind to the groups until pre-implantation but the statistician has sufficient knowledge of the groups to analyze the data.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile couples with primary and male factor infertility, Candidate for ICSI, Healthy women with at least 6 oocytes, Female age lower than 38 years, Male age lower than 45 years. Exclusion criteria: Infertile men with azoospermia, Infertile men with oligozoospermia, defrosted sperm.

##### Intervention groups

Study group: To perform ICSI technique, sperms are placed next to the wife's cumulus oophorus layer, and sperms that pass through this layer will be selected by the embryologist, and then injected into the oocyte. Control group: To perform ICSI technique, sperms are selected only based on morphology and viability, and

then will be injected into the oocyte.

##### Main outcome variables

Improvement of embryo quality, Pregnancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110804007223N9**

Registration date: **2019-10-17, 1398/07/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-17, 1398/07/25**

Update count: **0**

##### Registration date

2019-10-17, 1398/07/25

##### Registrant information

##### Name

Mohammad Hossein Nasr-Esfahani

##### Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 9501 5688

##### Email address

mh\_nasr@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-06, 1398/06/15

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### Scientific title

Comparison of clinical outcomes of infertile individuals candidate for ICSI using capillary-cumulus oophorus model versus routine method: A randomized single-blind controlled clinical trial

#### Public title

Comparison of clinical outcomes in two sperm selection procedures: capillary - cumulus oophorus versus routine method

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Infertility with male factor primary infertility Candidate for ICSI Healthy women with at least 6 oocytes Male age lower than 45 year

##### Exclusion criteria:

Infertile men with azoospermia Infertile men with oligozoospermia defrosted sperm

#### Age

To 45 years old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: 40

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The embryologist is completely unaware of the methods of sperm preparation (the routine method or the method of the passage of sperm from the cumulus oophorus layer), and the spermatozoa are given to the embryologist within the tubes containing the code. Therefore, the embryologist only selects sperm based on the morphology and motility in both groups and injects sperm into the oocyte. In the following days, the embryologist checks the fertilization rate, and the quality of the embryo, without knowing what kind of sperm preparation procedures is used.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Royan Institute

##### Street address

Royan Institute, Hafez St, Banihashem Ave, Resalat Highway, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

8159358686

#### Approval date

2019-07-17, 1398/04/26

#### Ethics committee reference number

IR.ACECR.ROYAN.REC.1398.119

## Health conditions studied

### 1

#### Description of health condition studied

Male infertility

#### ICD-10 code

N46.9

#### ICD-10 code description

Male infertility, unspecified

## Primary outcomes

### 1

#### Description

Improvement of embryo quality

#### Timepoint

Day 2 and 3 after ICSI

#### Method of measurement

Embryo growth, number and equal of blastomers, and lack of cytoplasm fragmentation

### 2

#### Description

Pregnancy

#### Timepoint

One month after embryo transfer

#### Method of measurement

Sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Sperm selection after passing sperm through the cumulus oophorus layer (The cumulus oophorus is a layer around the oocyte which will be separated from the oocyte of the patient's wife in vitro and placed in a capillary tube. From one end of the tube, sperm enter. After one hour, the sperms that have passed through the cumulus oophorus will be separated and injected into the oocyte.)

#### Category

Other

### 2

#### Description

Control group: Sperm routine selection based on morphology and viability

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Fertility and Infertility Center

##### Full name of responsible person

Mohammad Hossein Nasr-Esfahani

##### Street address

Fertility and Infertility Center, Salman Farsi St, Isfahan, Iran.

##### City

Esfahan

##### Province

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##### Postal code

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##### Phone

+98 31 3266 1873

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##### Email

nasr.royan@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Parvaneh Afsharian

##### Street address

Royan Institute, Hafez St, Banihashem Ave, Resalat Highway, Tehran, Iran

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##### Email

pafshar@royaninstitute.org

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Royan 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

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iranian academic center for education culture and research

##### Full name of responsible person

Mohammad Hossein Nasr-Esfahani

##### Position

Professor, An acadamic member of Royan Institute

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Male infertility

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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research

**Full name of responsible person**

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**Position**

Professor

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Ph.D.

**Other areas of specialty/work**

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**Other areas of specialty/work**

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tavalaee.royan@gmail.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**

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**

Yes - There is a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

After receiving and recording the data, the results can be shared

**When the data will become available and for how long**

The time of document publication will be after the publication of the manuscript.

**To whom data/document is available**

Principal Investigator & urologist

**Under which criteria data/document could be used**

If the results of this study show that sperm selection on the basis of sperm passage through the cumulus oophorus layers can lead to improved embryo quality and pregnancy outcomes, this method may be used in the future for couples with male infertility.

**From where data/document is obtainable**

Dr.Mohammad Hossein Nasr-Esfahani

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

Contact (03132670030) or refer to the Isfahan Fertility and Infertility Center

**Comments**