Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Isfehan
Postal code
8158881155
Phone
+98 31 3266 1873
Fax
+98 31 3267 9082
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
City
Tehran
Province
Tehran
Postal code
8159358686
Phone
+98 21 2356 2000
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
Street address
Royan Institute for Biotechnology, Royan St, Salman St, Khorasgan squ, Jey St.
City
Esfahan
Province
Isfehan
Postal code
8159358686
Phone
+98 31 9501 5682
Email
nasr.royan@gmail.com

Person responsible for scientific 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

Latest degree
Ph.D.

Other areas of specialty/work
Male infertility

Street address
Royan St, Salman St, Khorasgan squ, Jey St.

City
Esfahan

Province
Isfehan

Postal code
8159358686

Phone
+98 31 9501 5682

Email
nasr.royan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Marziyeh Tavalaee

Position
Associate, An academic member of Royan Institute

Latest degree
Ph.D.

Other areas of specialty/work
Male infertility

Street address
Biotechnology Institute, Royan Ave, Salman Ave, Khrasgan square, Jey Aven, Esfahan, Iran.

City
Esfahan

Province
Isfehan

Postal code
8158858151

Phone
+98 31 9501 5682

Email
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