

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessment and comparison of sperm apoptosis, embryo cytotkinetic and pregnancy outcomes of IMSI and ICSI methods in patients with male factor infertility.

Protocol summary

Study aim

Assessment and comparison of sperm apoptosis, embryo cytotkinetic and pregnancy outcomes of IMSI and ICSI methods in patients with male factor infertility.

Design

Patients referred to the Yazd Infertility Center who had male infertility and entered the ART cycles. The cases who had oocytes retrieval on Saturday and Wednesday randomly divided into two groups of control and intervention by computer-generated random numbers.

Settings and conduct

This study was conducted at the Yazd Infertility Center for improving the results of the treatment of male infertile patients who were treated several times and did not respond.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Male factor infertility 2) At least 3 years of primary infertility 3) The woman being 38 years or younger 4) An undetected female factor Exclusion criteria: Non-ejaculated spermatozoa (TESE,..)and ejaculates below 1million sperm/ml. The cases that hadn't good embryos for transfer.

Intervention groups

Control group: sperm selection was done at $\times 400$ magnification and then injected into mature oocytes. Intervention group: sperm selection was done at $\times 6000$ magnification and then injected into mature oocytes.

Main outcome variables

Improved sperm and embryo selection methods and pregnancy outcomes in ART cycles

General information

Reason for update

Record and update the latest changes applied in the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038561N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **retrospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **1**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Esmat Mangoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

es.mangoli@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-05-21, 1396/02/31

Actual recruitment start date

2016-05-01, 1395/02/12

Actual recruitment end date

2017-08-01, 1396/05/10

Trial completion date

2018-05-01, 1397/02/11

Scientific title

Assessment and comparison of sperm apoptosis, embryo cytotkinetic and pregnancy outcomes of IMSI and ICSI

methods in patients with male factor infertility.

Public title

Embryo cytotkinetic and pregnancy outcome in ICSI and IMSI cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with male factor infertility At least a history of 3 years primary infertility Woman had less than 38 years old without any infertility problem

Exclusion criteria:

Azoospermic patients(testicular and epididymal samples) The cases that hadn't good embryos for transfer Total freeze cycles

Age

To **38 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **95**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The mechanism of randomization was simple and individual randomization. No stratified randomization was used. Randomization was performed using a random number table. The random sequence was consecutive. No allocation concealment was applied.

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 medicine faculty Shahid Sadoughi University of Medical Science

Street address

BouAli Ave, Safaeih

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2015-11-25, 1394/09/04

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.338

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Positive chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

Beta HCG test

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Detection of one or more gestational sac with a fetal heartbeat after 6 weeks

Method of measurement

Ultrasound

Intervention groups

1

Description

Intervention group: sperm selection was done at x 6000 magnification and then injected into mature oocytes.

Category

Treatment - Devices

2

Description

Control group: sperm selection was done at x 400 magnification and then injected into mature oocytes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Abbas Aflatoonian
Street address
Bouali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
yazd-rsi@ssu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Robab Davar
Street address
Buali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Email
yazd-rsi@ssu.ac.ir
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
Esmat Mangoli
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Bouali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Email
es.mangoli@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Esmat Mangoli
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
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Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Email
es.mangoli@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Esmat Mangoli
Position
Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after people have not been identified.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

The data are only available for people working in academic institutions.

Under which criteria data/document could be used

By requesting the Yazd Reproductive Sciences Research Institute, it is possible to teach the relevant technique in medical centers.

From where data/document is obtainable

Applicants for documents and data can receive information from Dr. Mangali through the e-mail address es.mangoli@gmail.com or by referring to the Research Institute of Reproductive Sciences of Yazd in the embryology department.

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

Receipt of this data is done by mentioning the reason for using them and also agreeing to use the cooperation of a research institute professor in your study as a guide or clinical consultant.

Comments