

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation the efficiency of human sperm DNA fragmentation test, telomere assay and sperm selection technique on embryo development and pregnancy outcome.

#### Protocol summary

##### Study aim

Efficiency of human sperm DNA fragmentation test, telomere assay and selection technique will be evaluated on embryo development and pregnancy outcome.

##### Design

Blinded randomized clinical trial will be conducted on 100 infertile couples. Participants will be divided into intervention and control groups.

##### Settings and conduct

Infertile couples with male infertility, that the result of semen analysis will show the sperm morphology is abnormal will be entered the study. They will be divided into (Intracytoplasmic Sperm Injection) ICSI and (Intracytoplasmic Morphology Examination Sperm Injection) IMSI groups by by reputable block randomization. Sperm selection will be done under the inverted microscope by magnification of x400 in ICSI group, and more than x6600 in IMSI group. After that microinjection will be done by embryologist. (Sperm DNA Fragmentation) SDF and (Sperm Telomere Length) STL will be evaluated. Before micro injection, sperms will be selected for IMSI and ICSI by researcher and placed in the ICSI dish, therefore embryologist will not inform from sperm selection methods.

##### Participants/Inclusion and exclusion criteria

This study will be carried on 100 couples with male infertility. Inclusion criteria for male partner: Fresh ejaculated spermatozoa, concentration at least 5 million/ml, semen parameters characterized with Teratozoospermia Exclusion criteria: Testicular samples, ejaculate samples with concentration below 5 million / ml

##### Intervention groups

Intervention group: Intracytoplasmic Morphology Examination Sperm Injection (IMSI): Sperms will be selected by magnification more than 6000 x. Control group or Intracytoplasmic Sperm Injection (ICSI): sperms will be selected under 400 x magnification.

##### Main outcome variables

Fertilization rate, Cleavage Embryo Rate, Implantation rate, Chemical pregnancy rate, Clinical pregnancy rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211211053355N1**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

##### Registration date

2022-01-09, 1400/10/19

##### Registrant information

##### Name

Fatemeh Shakeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 7085

##### Email address

fatemehshaeri1359@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the efficiency of human sperm DNA fragmentation test, telomere assay and sperm selection technique on embryo development and pregnancy outcome.

**Public title**

Evaluation sperm selection technique on embryo development and pregnancy outcomes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Male participants are characterized by fresh ejaculated spermatozoa with a concentration of at least 5 million/ml , Teratozoospermia and having indication for ICSI because of male infertility. female partners aged under 38 years old, without poor ovarian response and having day 3 serum FSH < 15 IU/lit will be entered the study

**Exclusion criteria:**

Testicular samples and ejaculate samples with concentration below 5 million / ml female partner with poor ovarian response, endometriosis, and cases with no embryo to transfer.

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization with quadruple blocks, the blocks are arranged as follows: Block1: ABAB, Block2: AABB, Block 3: ABBA, Block 4: BBAA, Block5: BABA, Block 6: BAAB. 25 blocks will be required to select 100 participants with male factor infertility. These blocks will be selected randomly from 1-6 by software. For example after selection block 2: The first two participants will be dedicated to ICSI group and the second two participants will be dedicated to IMSI group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study participants and embryologists will not be informed that sperm selection will be done by ICSI or MSOME. At the first, sperm selection will be done by investigator under magnification 400 of inverted microscope for ICSI group and magnification more than 6600 for IMSI group, then sperms will be loaded in a drop

of ICSI dish. Finally microinjection will be done by embryologist. Investigator is an embryologist and will not do microinjection. Investigator will explained about two techniques of sperm selections.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics research of Yazd University of Medical Sciences

**Street address**

Yazd Infertility Center, Bou Ali st, Timsar Fallahi st, Safaieyeh

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Approval date**

2021-12-08, 1400/09/17

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1400.308

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

Male factor infertility with characterized by Teratozoospermia

**ICD-10 code**

N46.8

**ICD-10 code description**

Male Infertility

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

Embryo development

**Timepoint**

3 days after microinjection

**Method of measurement**

Based on Hill's grading

**2****Description**

Chemical pregnancy

**Timepoint**

2 weeks after embryo transfer

**Method of measurement**

Evaluation of B HCG in blood serum

**3****Description**

Clinical Pregnancy

**Timepoint**

8 weeks after embryo transfer

**Method of measurement**

detection of embryo heart beat in abdominal sonography

**4****Description**

Fertilization Rate

**Timepoint**

16-18 hours after microinjection

**Method of measurement**

evaluation the formation of 2 pronucleous under the microscope

**5****Description**

Embryo implantation rate

**Timepoint**

6weeks after embryo transfer

**Method of measurement**

detection the number of gestational sac in abdominal sonography

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

Evaluation SDF and STL in sperms with scores between 0-6

**Timepoint**

Before randomization

**Method of measurement**

Sperm DNA fragmentation test, Sperm Telomere Assay

**Intervention groups****1****Description**

Intervention group: Intracytoplasmic Morphologic Examination Sperm Injection (IMSI). In this group, researcher will be selected sperms under inverted microscope with more than 6000x magnification.

**Category**

Early detection

**2****Description**

Control group: Intracytoplasmic Sperm Injection(ICSI). In

this group, researcher will be selected sperms under inverted microscope with 400x magnification.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yazd Infertility Center

**Full name of responsible person**

Dr. Azam Agharahimi

**Street address**

Bou Ali St, Timsar Fallahi st, Safaieyeh

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**Email**

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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**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Phone**

38247085

**Email**

63rahimi@gmail.com

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

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh Shakeri

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Biology

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

Yazd University of Medical Sciences

**Full name of responsible person**

Azam Agha Rahim

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

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**Full name of responsible person**

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**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

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**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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

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