

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

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Iran (Islamic Republic of)

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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

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

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

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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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Position

Faculty member

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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