# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Fertilization rate comparison in IntraCytoplasmic Sperm Injection(ICSI) cycles with second ejaculated sperm sample versus(Testicular sperm extraction) TESE sample in patients with high Deoxyribonucleic acid (DNA) fragmentation index(high DFI)

## Protocol summary


**Study aim**

Comparison of the fertilization rate and the amount of good quality embryos (grade one and two) in couples who could undergo ICSI(Intracytoplamic sperm Injection), either using TESE(Testicular Sperm Extraction) or second sperm in male subjects with high DFI (DNA Fragmentation Index)and previous ART(Assisted ReproductiveTechnology) failure.

**Design**

Clinical trial with control group, with parallel groups, randomized, phase 2 on 30 patients. Patients are randomly assigned to one of the study and intervention groups with the help of a random number table and receive the services of the same group.

**Settings and conduct**

The number of 30 couples referred to Taleghani Hospital with a history of infertility who are candidates for ICSI are examined in the form of intervention and control groups of15 people.

**Participants/Inclusion and exclusion criteria**

There are couples who have had a history of at least 1 failure in the previous ART (Assisted Reproductive Technology)and in semen analysis, normosospermic men with DFI >30%(DNA Fragmentation Idex) Men are between 20 and 50 years old with normal semen Analysis, and women are between 18 and 40 years old. The cause of infertility in all patients is diagnosed only as a male factor

**Intervention groups**

30infertile couples candidates for ICSI, divided to 2 groups of 15 patients (1:intervention: from the normosospermic patients with high DFI within 1 to 3 hours of the first sample, the second sperm sample will be taken) and The control group (under anesthesia during the TESE process, a biopsy will be taken from the testicular tissue and the sperm will be extracted in the laboratory) are examined.

**Main outcome variables**

Two groups will be examined and compared in terms of ICSI outcomes, including fertilization rate, the amount of good quality embryos (G1 and G2) and some sperm parameters (concentration, forward movement, normal shape)


## General information

**Reason for update**

**Acronym**

TESE

**IRCT registration information**

IRCT registration number: **IRCT20230111057113N2**
Registration date: **2024-01-03, 1402/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-03, 1402/10/13**
Update count: **0**

**Registration date**

2024-01-03, 1402/10/13


**Registrant information**

**Name**

Samaneh Esmaeili

**Name of organization / entity**

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Iran (Islamic Republic of)

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+98 21 4435 2355

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dresmaeili@gmail.com


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-12-22, 1402/10/01
**Expected recruitment end date**
2024-02-20, 1402/12/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Fertilization rate comparison in IntraCytoplasmic Sperm Injection(ICSI) cycles with second ejaculated sperm sample versus(Testicular sperm extraction) TESE sample in patients with high Deoxyribonucleic acid (DNA) fragmentation index(high DFI)

**Public title**
Examination of the second sample of ejaculated sperm in patients with high DNA fragmentation( DFI)
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
At least 1 failed ART(Assissted Reproductive technology) attempts women between 18 and 40 years old High DFI levels of more than 30% in semen samples at admission Men between 20and 50 years old
**Exclusion criteria:**
A male patient with obvious abnormalities noted in the medical history, physical examination, endocrine profile, and evidence of subclinical genital infections, leukocytospermia, cryptorchidism, cancer, history of chemotherapy or radiotherapy, or severe varicocele 2- Women with a history of poor response to ovarian stimulation or meeting the POSEIDON((Patient-Oriented Strategies Encompassing IndividualizeD Oocyte Number) criteria for expected poor responders Pre-implantation genetic screening (PGS), frozen/thawed embryo transfer cycles, Apparent pathology of the uterus or tube 5- People with genetic disorders 6- Male patients with heavy smoking (more than 20 cigarettes per day) 7- Severe endometriosis 8-Patients with sperm freezing
**Age**
From **20 years** old to **50 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **30**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
patients are randomly placed in one of the two study and intervention groups with the help of a random number table and receive the services related to the same group.
**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 Shahid Beheshti University of Medical Sciences
**Street address**
Taleghani Hosp,Araabi st,Yaman Ave,Chamran,Tehran Highway,
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Approval date**
2023-12-13, 1402/09/22
**Ethics committee reference number**
IR.SBMU.RETECH.REC.1402.548

## Health conditions studied

### 1

**Description of health condition studied**
High DNA fragmentation index in sperm of infertile men
**ICD-10 code**
N46.8
**ICD-10 code description**
Other male infertility

## Primary outcomes

### 1

**Description**
Fertilization rate determination in ICSI (IntraCytoplasmic Sperm Injection)cycles with the second sample of ejaculated sperm in patients with high DFI(DNA Fragmentation Index)
**Timepoint**
Checking the fertilization rate after 3 days following oocyte injection
**Method of measurement**
percentage (calculated by dividing the number of 2 pronuclei by the total number of injected eggs)

**2**

**Description**
Determining the amount of grade one and two embryos in ICSI cycles with the second sample of ejaculated sperm in patients with high DFI
**Timepoint**
The number of grade 1 and 2 embryos on day 3 after injection
**Method of measurement**
Percentage (calculated by dividing the number of grade one and two embryos by the total number of embryos formed)

**3**

**Description**
Determination of grade one and two embryos in ICSI cycles with TESE (Testicular Sperm Extraction)samples in patients with high DFI
**Timepoint**
The number of grade 1 and 2 embryos on day 3 after injection
**Method of measurement**
Percentage (calculated by dividing the number of grade one and two embryos by the total number of embryos formed)

**4**

**Description**
Fertilization rate determination in ICSI cycles with TESE-derived sperm(Testicular Sperm extraction) in patients with high DFI
**Timepoint**
Checking the fertilization rate after 3 days following oocyte injection
**Method of measurement**
percentage (calculated by dividing the number of pronuclei by the total number of injected eggs)

## Secondary outcomes

**1**

**Description**
Investigating the forward motility of sperms in the second sample of ejaculated sperm
**Timepoint**
The sample within one hour of the first sample
**Method of measurement**
The percentage of forward-moving spermatozoa to the total spermatozoa observed by light microscopy

**2**

**Description**
Examination of other sperm parameters in TESE (Testicular sperm Extraction)sample
**Timepoint**
Sample immediately after TESE
**Method of measurement**
The percentage of forward-moving spermatozoa to the total spermatozoa observed by light microscopy

**3**

**Description**
Examination of sperms with normal shape in the second sperm sample
**Timepoint**
Sample within one to three hours of the first sample
**Method of measurement**
The percentage of sperms with normal shape to the total sperms with a light microscope

**4**

**Description**
Examination of sperms with normal shape in the sample obtained from TESE
**Timepoint**
Sample immediately after TESE
**Method of measurement**
The percentage of sperms with normal shape to the total sperms and observed with a light microscope

**5**

**Description**
Examining the concentration of sperms in the second sample of ejaculated sperm
**Timepoint**
The sample within one hour to three after the first sample
**Method of measurement**
Calculate it under a light microscope and in one cc of ejaculate

**6**

**Description**
Investigating the concentration of sperms in the TESE sample
**Timepoint**
Sample immediately after TESE
**Method of measurement**
Calculate it under a light microscope and in a cc of semen sample

## Intervention groups

**1**

**Description**
Control group: TESE sample (TESE sample is prepared from patients under anesthesia)
**Category**
Treatment - Surgery

**2**

**Description**
Intervention group: second sample of ejaculated sperm (patients will be asked to take another sample from the first sample within one to three hours)

**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Taleghani Hospital
**Full name of responsible person**
Samaneh Esmaeili
**Street address**
Shahid Arabi St, Yemen St.,Chamran Highway, Tehran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
معاون تحقیقات و فناوری دانشگاه علوم پزشکی شیدبهشتی
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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**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
samaneh esmaeili
**Position**
Non-faculty specialist doctor
**Latest degree**
Specialist
**Other areas of specialty/work**
Gynecology and Obstetrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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**Latest degree**
Specialist

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Gynecology and Obstetrics

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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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Only a part of the data, such as the information related to the main result or the like, can be shared.

**When the data will become available and for how long**
The access period starts 6 months after the results are published

**To whom data/document is available**
The data will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
It is allowed to use the documents for the thesis with references

**From where data/document is obtainable**
Email to this address dresmaeili@gmail.com

**What processes are involved for a request to access data/document**
After a month, they will receive the results

**Comments**