Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 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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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,
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti 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
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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Specialist
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Person responsible for updating data

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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