

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The comparison of diagnostic TESE and TESA in non-obstructive azoospermic patients

Protocol summary

Summary

The aim of this study is the comparison of open biopsy (TESE: Testicular Sperm Extraction) and aspiration (TESA: Testicular Sperm Aspiration) in non obstructive azoospermia (NOA). 180 patients with non-obstructive Azospermia at Royan Infertility Center who were candidates for surgical diagnosis of existence of sperm were recruited. Techniques of TESE and TESA for uniformity of procedure were discussed by 4 surgeons of the group. Testis selection (right or left) and techniques (TESE or TESA) were determined randomly. In TESA, the testis was aspirated at three separated sites (upper, middle and lower pole), using 20 ml syringe and 18-gauge needle. In TESE testicular biopsy was taken from the same sites. The ability of sperm retrieval in both techniques was compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903114077N1**

Registration date: **2010-09-10, 1389/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-10, 1389/06/19

Registrant information

Name

Majid Vafaei

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2009-09-15, 1388/06/24

Expected recruitment end date

2010-05-05, 1389/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of diagnostic TESE and TESA in non-obstructive azoospermic patients

Public title

The comparison of diagnostic open biopsy and needle biopsy in non-obstructive azoospermic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Non obstructive Azoospermia, No Previous biopsy Exclusion Criteria: atrophic testis, FSH levels more than 4 times of normal range

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Royan institute

Street address

Royan Institute, No12, Hafez St, Banihashem St,
Resalat Ave, Tehran

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Tehran

Postal code

iran

Approval date

2009-08-18, 1388/05/27

Ethics committee reference number

EC/88/1016

Health conditions studied

1

Description of health condition studied

male infertility-azoospermia

ICD-10 code

N46

ICD-10 code description

Azoospermia NOS

Primary outcomes

1

Description

Recovery of sperm

Timepoint

once after sampling

Method of measurement

To study biopsy under a light microscope with 400X magnification

Secondary outcomes

empty

Intervention groups

1

Description

Testicular sperm extraction (TESE) Control group: A 1.5-2 cm incision was made in the scrotal skin and continued through the tunica albuginea and with a little push somniferous tubule appeared. A testicular biopsy for TESE was taken from (upper, middle and lower pole)

Category

Treatment - Drugs

2

Description

TESA Intervention group: In this procedure, a 20 ml syringe with 18 gauge needle was used. At first, we inserted the needle into the upper section of testis and slowly pulled it out to cause negative pressure. For maintaining the negative pressure, we moved the needle in and out of the testis for several times, then pulled the needle out, slowly. This acted as suction and caused the testis tissue to enter into the syringe. Taking biopsies were performed in the upper, middle and lower sections of the testis same as control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Jalil Hosseini -MD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Shahverdi

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Royan Institute

City

Tehran

Grant name

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Royan Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

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

empty

Person responsible for general inquiries**Contact****Name of organization / entity**Royan Institute - Islamic Azad University of Damghan,
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Majid Vafaei

Position

Developmental Biology (Msc), student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty