

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A clinical trial to compare the effectiveness of routine method with hyaluronic acid and hypo-osmotic swelling test on sperm selection, fertilization evaluation, embryo development, embryo quality, and implantation rate in intracytoplasmic injection of oligoasthenozoospermic men.

Protocol summary

Summary

Objective: To compare the effectiveness of routine method with hyaluronic acid and hypo-osmotic swelling test on sperm selection, fertilization evaluation, embryo development, embryo quality, and implantation rate in intracytoplasmic injection of oligoasthenozoospermic men. Design: A randomized double-blind clinical trial based on random number table. Study population: Infertile men (Oligasthenos spermatozoa) will be subjected to intra-cytoplasmic sperm injection. Inclusion criteria: Males: age range of 22-40 years; infertility duration of 2-10 years; sperm count of 5×10^6 - 20×10^6 ml; and sperm motility rate of 25-40%. Females: aged range of 20-37 years; lack of infertility problem; and oocytes number of 6-7. Exclusion criteria: Males: no anomalies or spermatoc leukocytes. Females: inflection with infertility problems (e.g., ovarian problems and endometriosis). Sample size: 80 cases. Study intervention: The control group will receive the routine sperm selection methods (i.e., sperm chromatin dispersion and microinjection), while the intervention group I will be subjected to hyaluronic acid (HA) binding and the intervention group II will undergo hypo-osmotic swelling test. Study outcome: Evaluation and comparison of the effectiveness of fertilization evaluation, embryo development, embryo quality, and implantation rate of the two intervention groups with the control group after the intervention.

General information

Acronym

HA, Hyaluronan -binding assay

IRCT registration information

IRCT registration number: **IRCT2017090336039N1**

Registration date: **2017-09-26, 1396/07/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Maryam Sefidgar Tehrani

Name of organization / entity

PhD Student of Anatomy

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2018-08-07, 1397/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A clinical trial to compare the effectiveness of routine method with hyaluronic acid and hypo-osmotic swelling test on sperm selection, fertilization evaluation, embryo development, embryo quality, and implantation rate in intracytoplasmic injection of oligoasthenozoospermic men.

Public title
Comparison of sperm selection methods in intracytoplasmic injection.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Males: age range of 22-40 years; infertility duration of 2-10 years; sperm count of 5×10⁶-20×10⁶ ml; and sperm motility rate of 25-40%. Females: aged range of 20-37 years; lack of infertility problem; and oocytes number of 6-7. Exclusion criteria: Males: no anomalies or spermatoc leukocytes. Females: inflexion with infertility problems (e.g., ovarian problems and endometriosis).

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City
Mashhad

Postal code

Approval date
2016-01-06, 1394/10/16

Ethics committee reference number
IR.mums.fm.REC.1394.320

Health conditions studied

1

Description of health condition studied

Oligoasthenospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Embryo development and quality

Timepoint

3 days after intervention

Method of measurement

Grid system-Blastomere size and cytoplasm quality

2

Description

Evaluation of fertilization

Timepoint

2 weeks after intervention

Method of measurement

Microscopic observation - The number of normally fertilized oocytes

3

Description

Implantation rate

Timepoint

3 days after intervention

Method of measurement

Pregnancy pact observation by sonography and HCG test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group II: who is receiving hypo-osmotic swelling test.

Category

Treatment - Other

2

Description

Control group: who is receiving the routine sperm selection methods (i.e., sperm chromatin dispersion and microinjection).

Category

Treatment - Other

3

Description

Intervention group I: who is receiving hyaluronic acid (HA) binding.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Fertility Clinic

Full name of responsible person

Maryam Sefidgar Tehrani

Street address

Montserieh Infertility Treatment Research Center,
Side of Sina Hospital, East Razi Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Medical Sciences, Ghoreishi building, Daneshgah
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City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Sciences

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

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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