

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of clinical outcomes in two sperm selection procedures (density gradient centrifugation with surface markers- density gradient centrifugation) in infertile men intra-cytoplasmic sperm injection candidate

Protocol summary

Summary

Objectives: Comparison of clinical outcomes in routine (density gradient centrifugation: DGC) with novel sperm selection procedures (surface markers-density gradient centrifugation: MACS-DGC) in infertile men ICSI candidate. Design: Infertile couples with primary male factor infertility were included in this study and referred to Isfahan fertility and infertility center. These individuals were informed about the study and were grouped . Setting and conduct: In the day of ICSI operation, after choosing 50 infertile couples, sibling oocytes divided into two groups: half of the oocytes were inseminated with sperm that selected with MACS-DGC processing (MACS-DGC group) and remaining oocytes were inseminated with sperm that selected with DGC method (based on viability and morphology) (internal control or DGC group). In the external control group all the oocytes were inseminated by sperm that selected with DGC method (based on viability and morphology). Major Inclusion and Exclusion criteria: Inclusion criteria: Primary male factor infertility (according to the WHO-2010); Exclusion criteria: females factor infertility with higher than 35 years and less than 6. oocytes Intervention: In study group, half of oocytes were inseminated with sperm that selected with DGC following MACS processing (Separate intact spermatozoa from those that present apoptotic markers) (MACS-DGC group). Main outcome measures (variables): In this study, for first time the clinical outcomes such as fertilization, embryo quality and pregnancy rates in these groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504307223N3**

Registration date: **2015-10-11, 1394/07/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-11, 1394/07/19

Registrant information

Name

Mohammad Hossein Nasr-Esfahani

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Country

Iran (Islamic Republic of)

Phone

+98 31 9501 5688

Email address

mh_nasr@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2014-01-28, 1392/11/08

Expected recruitment end date

2015-07-30, 1394/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcomes in two sperm selection

procedures (density gradient centrifugation with surface markers- density gradient centrifugation) in infertile men intra-cytoplasmic sperm injection candidate

Public title

Comparison of clinical outcomes in tow sperm selection procedure

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Primary male factor infertility (at least, two of their semen parameters were considered as abnormal according to the WHO-2010) Exclusion criteria: Females factor infertility basely WHO criteria (2010) with higher than 35 years and less than 6 oocytes

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Royan Institue

Street address

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

City

Tehran

Postal code**Approval date**

2014-08-02, 1393/05/11

Ethics committee reference number

EC/93/1101

Health conditions studied**1****Description of health condition studied**

Male factor infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes**1****Description**

Sperm motility

Timepoint

In daye of ICSI procedure

Method of measurement

Using optical microscope, based WHO criteria

2**Description**

Sperm concentration

Timepoint

In daye of ICSI procedure

Method of measurement

Using optical microscope, based WHO criteria

3**Description**

Sperm morphology

Timepoint

In daye of ICSI procedure

Method of measurement

Using optical microscope, based WHO criteria

4**Description**

Fertilization rate

Timepoint

24 hours after ICSI procedure

Method of measurement

View of 2 pronucleuse with invert microscop

5**Description**

Chemical pregnancy

Timepoint

18 days after ICSI procedure

Method of measurement

Measurement of Beta HCG level in serum

6**Description**

Quality of embryo

Timepoint

Three days post-oocyte retrieval

Method of measurement

Using a three-point scoring system including fragmentation rate, number of blastomere, shape and size

7

Description

Clinical I pregnancy

Timepoint

12 weeks after ICSI procedure

Method of measurement

Fetal heart beat

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Half of oocytes were inseminated with sperm that selected with DGC following MACS processing (Separate intact spermatozoa from those that present apoptotic markers by magnetic particles conjugated with Annexin V, which has a high affinity for Phosphatidylserine)(MACS-DGC group).

Category

Other

2

Description

Internal control group: Remaining oocytes were inseminated with sperm that selected with DGC method (based on viability and morphology) (DGC group)

Category

Other

3

Description

External control group: All the oocytes were inseminated by sperm that selected with DGC method

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Fertility and Infertility Center

Full name of responsible person

Mohammad Hossein Nasr Esfahani

Street address

Salman Farsi St, Isfahan, Iran, Fertility and Infertility Center

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdolhossein Shahverdi

Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran, Royan Institute for Biotechnology

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 (Royan Institute for Biotechnology)

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor

Other areas of specialty/work

Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran, Royan Institute for Biotechnology

City

Isfahan

Postal code

Phone

+98 31 9501 5688

Fax

+98 31 9501 5687

Email

mh_nasr@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor

Other areas of specialty/work

Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran, Royan
Institute for Biotechnology

City

Isfahan

Postal code

Phone

+98 31 9501 5688

Fax

+98 31 9501 5687

Email

mh_nasr@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor

Other areas of specialty/work

Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran, Royan
Institute for Biotechnology

City

Isfahan

Postal code

Phone

+98 31 9501 5688

Fax

Email

mh_nasr@med.mui.ac.ir

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