

# 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

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**Phone**

+98 31 9501 5688

**Fax**

+98 31 9501 5687

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**Web page address**

**Person responsible for updating data**

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**Email**

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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*