

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficiency of density gradient centrifuge (DGC) with combined DGC/Zeta method on ICSI outcome.

Protocol summary

Summary

The aim of this clinical controlled trial is evaluation and comparison of the ICSI outcome in male factor infertile patients, between the intervention group in which sperm is selected with Zeta method and the control group in which sperm is selected with routine density gradient centrifugation. In this study, 500 male factor infertile patients who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control group. Fertilization rate, embryo quality and pregnancy rate are assessed and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108047223N1**
Registration date: **2011-12-27, 1390/10/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-27, 1390/10/06

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

Department of Reproduction and Development,
Reproductive Biomedicine Research Center, Royan
Institute for Animal Biotechnology, ACECR, Isfahan, Iran

Expected recruitment start date

2008-04-08, 1387/01/20

Expected recruitment end date

2012-04-08, 1391/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficiency of density gradient centrifuge (DGC) with combined DGC/Zeta method on ICSI outcome.

Public title

Effect of sperm selection based on surface charge on pregnancy outcome after ICSI

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: infertility with male factor such as oligozoospermia, asthenozoospermia, trazoospermia
Exclusion criteria: infertility with female factor criteria, female's age more than 40 years

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: **500**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Royan institute

Street address

NO.2, Hafez street, Banihashem street, Resalat Ave,
Tehran, Iran

City

Tehran

Postal code**Approval date**

2011-10-15, 1390/07/23

Ethics committee reference number

90/187/پ

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**

semen parameters

Timepoint

in day of ICSI procedure

Method of measurement

based on WHO 1999 criteria

2**Description**

level of sperm DNA fragmentation

Timepoint

in day of ICSI procedure

Method of measurement

using TUNEL test

3**Description**

fertilization rate

Timepoint

24 hours After ICSI procedure

Method of measurement

view of 2 pronucleus with invert microscope

4**Description**

pregnancy

Timepoint

20 day after ICSI procedure

Method of measurement

beta HCG level in serum

Secondary outcomes

empty

Intervention groups**1****Description**

sperm selection based on Zeta method for ICSI
procedure

Category

Treatment - Other

2**Description**

routine sperm selection method(density gradient
centrifugation) for ICSI procedure in control group

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan fertility and infertility center

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Royan institute

Full name of responsible person
 Mohammad Hossein Nasr Esfahani

Street address
 NO.2,Hafez street,Banihashem street,Resalat Ave,Tehran,Iran

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

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

2

Sponsor

Name of organization / entity
 Isfahan fertility and infertility center

Full name of responsible person
 Mohammad Hossein Nasr Esfahani

Street address
 salman Farsi ave. Isfahan fertility and infertility center. isfahan

City
 Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
 Isfahan fertility and infertility center

Proportion provided by this source

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

Full name of responsible person

Mohammad Hossein Nasr Esfahani

Position
 Ph.D

Other areas of specialty/work

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Position
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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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