

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of ICSI outcome in two sperm selection method: routine sperm selection and HOS method in infertile men

Protocol summary

Summary

In intra-cytoplasmic sperm injection (ICSI) technique selects sperm according to morphology and motility. Considering the role of sperm genomic quality as half of embryo genome, novel sperm selection procedures have been proposed to circumvent the possibility of inseminating DNA-damaged sperm. In routine sperm selection methods, sperm selected based on appearance properties such as motility and density. But sperm selection based on sperm functional properties may be efficient to recover normal sperm with normal DNA structure. It has been shown that different potential hypo-osmotic swelling test (HOST) patterns possess the potential to differentiate between sperm that have intact or damaged chromatin. Therefore this preliminary study evaluates the role of HOST as a sperm selection procedure in a clinical setting. In this study male factor infertile patient divided in control group that oocyte injected with selected sperm with Density Gradient Centrifuging method and "test" group oocyte injected with selected sperm with response to Hypo-Osmotic medium. Then result of fertilization rate, pregnancy and implantation rate compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307087223N2**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-27, 1392/08/05

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; Isfahan Fertility and Infertility Center

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ICSI outcome in two sperm selection method: routine sperm selection and HOS method in infertile men

Public title

Comparison of Intra-cytoplasmic sperm injection outcomes during two sperm selection procedures: Density Gradient Centrifuging and response to Hypo Osmotic Swelling medium in male factor infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male factor infertility; oocyte number up to 8 Exclusion criteria: age > 35, female factor infertility

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Single 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**

2013-08-14, 1392/05/23

Ethics committee reference number

1042/92/EC

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

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

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

pregnancy rate

Timepoint

2 weeks after embryo transfer

Method of measurement

beta hCG test

Secondary outcomes**1****Description**

fertilization rate

Timepoint

24 for after injectin sperm into oocyte during ICSI

Method of measurement

observation of two pronucleus under microscope

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

in control group: Endometer quality in the day of embryo transfer: if uterine endometer has a bad quality, good embryo freeze and low quality embryo may transferred that affect pregnancy outcome

Category

Other

2**Description**

in test group: Endometer quality in the day of embryo transfer: if uterine endometer has a bad quality, good embryo freeze and low quality embryo may transferred that affect pregnancy outcome

Category

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
Street address

NO.2, Hafez street, Banihashem street, Resalat Ave,
Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2356 2123
Fax
Email
mh_nasr@med.mui.ac.ir
Web page address

Person responsible for scientific 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
Street address
NO.2, Hafez street, Banihashem street, Resalat Ave,
Tehran, Iran
City
tehran
Postal code
Phone
+98 21 2356 2000
Fax
Email
mh_nasr@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person
Mohammad Hossein Nasr Esfahani
Position
Ph.D
Other areas of specialty/work
Street address
NO.2, Hafez street, Banihashem street, Resalat Ave,
Tehran, Iran
City
Tehran
Postal code
Phone
+98 31 1951 5680
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*