Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Email address

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Recruitment status

Recruitment complete

Funding source

Royan Iinstitute; 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 infetility

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 commitee 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 infertilty
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

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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