

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of clinical outcomes of infertile men candidate for ICSI between two methods of sperm separation: Felix device based on surface electric charge and density gradient centrifugation (DGC)

Protocol summary

Study aim

Comparison of clinical outcomes of infertile couples' candidates for the ICSI using both sperm preparation methods: DGC and Felix.

Design

This clinical trial study with the control group, with parallel groups, one-arm blind, on 100 patients.

Settings and conduct

Isfahan Fertility and Infertility Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile couples with male factor infertility (abnormal sperm parameters according to WHO 2021). Exclusion Criteria: cryo-preserved semen samples, and sperm retrieved from testicular or epididymis

Intervention groups

For each couple, sperm will be processed by DGC and Felix methods.

Main outcome variables

Fertilization, Embryo quality, Blastocyst quality, Implantation, Chemical, and Clinical pregnancy, and live birth.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110804007223N11**

Registration date: **2022-06-09, 1401/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-09, 1401/03/19**

Update count: **0**

Registration date

2022-06-09, 1401/03/19

Registrant information

Name

Mohammad Hossein Nasr-Esfahani

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-01, 1401/03/11

Expected recruitment end date

2023-06-01, 1402/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcomes of infertile men candidate for ICSI between two methods of sperm separation: Felix device based on surface electric charge and density gradient centrifugation (DGC)

Public title

Comparison of clinical outcomes between two sperm separation procedures: Felix vs. DGC

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Couples candidate for ICSI The number of follicles: at least 10 MII oocytes. Infertile couples with male factor infertility (sperm parameters lower than defined threshold by WHO 2021) Female age $\leq$ 38 years Men with at least 2ml semen Embryo transfer only at blastocyst stage One blastocyst for transfer Normal female (female will be considered as normal if they have a regular cycle with patent tube and absence of endometriosis) Men with a total sperm cell count higher than 5 million per ejaculate

Exclusion criteria:

Men with testicular sperm extraction or epididymal sperm aspiration Men with cryo-preserved semen samples

Age

From **15 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The individual performing ICSI will be blinded to the methods of sperm processing (group one: density gradient centrifuge (DGC) method and group two: electric charge using a flex device method) and also the allocation of oocytes to each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Royan Institute

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Banihashem

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Tehran

Postal code

8159358686

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.ACECR.ROYAN.REC.1399.071

Health conditions studied

1

Description of health condition studied

Sperm selection procedure

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Blastocysts rate and quality

Timepoint

Day 5 or 6 after ICSI

Method of measurement

Microscope

Secondary outcomes

1

Description

Fertilization

Timepoint

16-18 hours after ICSI

Method of measurement

The number of 2PNs divided by the number of MII oocytes injected by ICSI multiplied by 100.

2

Description

Embryo quality

Timepoint

2 or 3 day after ICSI

Method of measurement

According to DK Gardner criteria (2016)

3

Description

biochemical pregnancy

Timepoint

Post implantation

Method of measurement

Beta hCG level

4

Description

Clinical pregnancy

Timepoint

Fifth or sixth week of pregnancy

Method of measurement

The observation of a fetal sacs and also fetal heartbeat by sonography.

5

Description

implantation

Timepoint

One to two weeks after blastocyst transfer

Method of measurement

Sonography

6

Description

Livebirth

Timepoint

At the time of delivery

Method of measurement

By phone call

Intervention groups

1

Description

For each semen sample, two procedures will be carried out for sperm preparation. One of the procedures (Control) will be used for half of the sibling oocytes, and another procedure (study) will be used for other sibling oocytes. Study (Flix) group: For each sample, one Felix cartridge will be used. 1ml of liquefied semen sample will be transferred to Felix SYSTEM. Each cartridge contains two chambers:1. Harvest chamber – 1ml of G-IVF Plus (Vitrolife; Sweden).2. Reservoir chambers (2) – 4mls of G-Rinse (Vitrolife; Sweden) in each (8mls total). The selected sperm will then be collected from the harvest chamber based on the electric charge, and the sperm wash medium (VitaSperm: Innovative Biotech, Iran) in addition to 10% human serum albumin will be added.

Category

Treatment - Devices

2

Description

Control (DGC) group: 1ml of 40% PureSperm gradient (Vitrolife; Sweden) will be transferred on 1ml of 80% PureSperm gradient (Vitrolife; Sweden) into a conical centrifuge tube. Then, 1ml of liquefied semen sample will be placed on the top of the upper layer, and the tube Will be centrifuged for 20 min at 1000rpm. The upper and lower layers will carefully be aspirated without disturbing the pellet. VitaSperm washing media (Innovative Biotech, Iran) + 10% human serum albumin will be then added to the pellet. Adjust sperm concentration DGC similar to sperm concentration Felix in the same volume.

Category

Treatment - Devices

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

Department of Reproductive Biotechnology,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor, An academic member of Royan Institute

Latest degree

Ph.D.

Other areas of specialty/work

Male infertility

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Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor, An academic member of Royan Institute

Latest degree

Ph.D.

Other areas of specialty/work

Male infertility

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Consent form Information regarding two sperm processing procure will be given to the couple. They will be informed that the best blastocyst will be selected for embryo transfer irrespective of the group, so that the fertility is not effected. The couples will be informed the Felix is very likely to be superior to DGC and very unlikely inferior. The couple will be included in the study after formal presentation and signing the consent form.

When the data will become available and for how long

12 month after publication of the results

To whom data/document is available

Principle Investigator: Dr. Mohammad Hossein Nasr-Esfahani

Under which criteria data/document could be used

By permission of Memphasys company that provided Felix instrument and cartilages

From where data/document is obtainable

Principle Investigator: Dr. Mohammad Hossein Nasr-Esfahani Royan Institute

What processes are involved for a request to access data/document

Via email of Dr. Mohammad Hossein Nasr-Esfahani

nasr.royan@gmail.com

Comments