

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of clinical outcomes between Natural Sperm Sorting (NSS) and Direct Swim Up (DSU) in ICSI program; Assessments of mitochondrial, chromatin integrity and fine morphology (MSOME)

Protocol summary

Study aim

Comparison of clinical outcomes between Natural Sperm Sorting and Direct Swim Up in ICSI program in the donation casee

Design

Clinical trial was performed with parallel control and intervention groups, study on 50 infertile couples who donated oocyte

Settings and conduct

Among the patients who refer to Yazd Infertility Center, 50 samples of normal semen are randomly selected. Female infertility and candidate egg donation were the main diagnostic factors for all couples, and all patients received written consent to participate in the study protocol.

Participants/Inclusion and exclusion criteria

The inclusion criteria : the female feature patient that needs oocyte donation and normal sperm and donor female feature as follows: donor age<30 with having at least 5 metaphase II oocyte The exclusion criteria : surgical sperm retrieval; female donor age>30, frozen donor eggs; cancelled cycles and cycles with missing key data

Intervention groups

Each person's sperm sample is divided into two parts: Interventional group: they are prepared in a method without using a centrifuge. Control group: No intervention is made.

Main outcome variables

Chemical pregnancy rate and clinical pregnancy rate

General information

Reason for update

Update sampling date

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049263N1**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**

Update count: **2**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Fateme Dehghanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3626 6855

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-16, 1400/06/25

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

2021-09-16, 1400/06/25

Actual recruitment end date

2021-12-22, 1400/10/01

Trial completion date

2022-01-30, 1400/11/10

Scientific title

Comparison of clinical outcomes between Natural Sperm Sorting (NSS) and Direct Swim Up (DSU) in ICSI program; Assessments of mitochondrial, chromatin integrity and

fine morphology (MSOME)

Public title

Evaluation of the effect of sperm preparation by free centrifugation on clinical outcomes in ICSI cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non male factor Female with donation cases for homogenization Study groups

Exclusion criteria:

Male factor Female factor

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each sample is divided into two parts for DSU separation and the other for NSS separation.

Actual sample size reached: **60**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Each mixed semen sample was split into two equal portions, with the first being processed using the DSU technique (control) and the second using the FCS method (experimental)

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd University of Medical Sciences

Street address

Research Institute of Reproductive Sciences, Bouali St., Safaieh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2021-01-06, 1399/10/17

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.259

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Fertilization rate

Timepoint

One day after assisted artificial insemination

Method of measurement

Microscopic examination

2

Description

Embryo formation rate

Timepoint

3 days after assisting artificial insemination

Method of measurement

Microscopic evaluation

3

Description

Chemical pregnancy rate

Timepoint

One week after the embryo transfer to the uterus

Method of measurement

Blood β HCG Measurement

Secondary outcomes

1

Description

Clinical pregnancy rate

Timepoint

7 weeks after embryo transfer to the uterus

Method of measurement

Assessment of cardiovascular formation using ultrasound examination

Intervention groups

1

Description

Control group: sorted sperm with Direct swim up.

Category

Treatment - Other

2

Description

Intervention group: Sperms that are isolated by NSS method.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Research Center- Shahid Sadoughi
University of Medical Sciences, Yazd

Full name of responsible person

Abbas Aflatoonian

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Bouali Street, Safaieh, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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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

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Ali Khalili

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data: 1) Fertility rate, by examining the formation of pronucleus in the egg cell 2) Checking the embryo quality and calculating the time related to the process of cell division of the embryo 3) Checking the chemical and clinical pregnancy rates respectively one week and 7 weeks after embryo transfer

When the data will become available and for how long

Up to one year after publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

With the re-consent of the participant and the researcher responsible of the projec

From where data/document is obtainable

Mohammad Ali Khalili 09133570876
khalili59@hotmail.com

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

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Comments