

# 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)

###### Phone

+98 35 3626 6855

###### Email address

dehghanpour64@yahoo.com

##### 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  $\beta$ 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

#### Street address

Bouali Street, Safaieh, Yazd

#### City

Yazd

#### Province

Yazd

#### Postal code

8916877391

#### Phone

+98 35 3824 8119

#### Email

dehghanpou64@yahoo.com

#### Web page address

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Masoud Mirzaei

#### Street address

Bouali Street, Safaieh

#### City

YAZD

#### Province

Yazd

#### Postal code

8916877391

#### Phone

+98 35 3824 8119

#### Email

dehghanpour64@yahoo.com

### 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

#### Street address

Bouali street, Safaieh

#### City

Yazd

#### Province

Yazd

#### Postal code

8916877391

#### Phone

+98 35 3824 8119

#### Email

khalili59@hotmail.com

## Person responsible for scientific 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

#### Street address

Bouali street, Safaieh

#### City

Yazd  
**Province**  
Yazd  
**Postal code**  
8916877391  
**Phone**  
+98 35 3824 7085  
**Email**  
khalili59@hotmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Dehghanpour  
**Position**  
PhD candidate in Reprod. Biol.  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Reproductive Biology  
**Street address**  
Bouali street, Safaieh  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8913965751  
**Phone**  
+98 35 3626 6855  
**Email**  
dehghanpour64@yahoo.com

## 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

mohammad ali khalili 09133570876  
khalili59@hotmail.com

### Comments