Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating sperm parameters, DNA integrity, embryo cytokinetic and pregnancy rate from sperms selected by cumulus column compared to the control group in male factor infertile couples.

Protocol summary

Study aim
Investigating sperm parameters, DNA integrity, embryo cytokinetic and pregnancy rate obtained from sperms selected by cumulus column compared to the control group in infertile couples with male factor

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 100 patients. Statistical software will be used for randomization.

Settings and conduct
The study will be conducted at the Research Institute of Reproductive Sciences in Yazd. In this study, the patient, embryologist and gynecologist will be considered blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: infertile couples with male cause candidates for ICSI, reproductively healthy women with at least 6 MII eggs and age less than 38 years Exclusion criteria: infertile patients with severe male factor, frozen sperm samples, tissue samples, female age over 38 years.

Intervention groups
In the control group of sperm samples after preparation by density gradient method, sperm selection is done only by density gradient and in the study group, sperm selection in addition to density gradient will be done by passing through the cumulus column, and then for ICSI are used.

Main outcome variables
Application of non-invasive techniques to improve the results of ART treatment cycles for male factor infertile patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180130038561N2**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **prospective**

Last update: **2023-09-03, 1402/06/12**
Update count: **0**

Registration date
2023-09-03, 1402/06/12

Registrant information
Name
Esmat Mangoli
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-23, 1402/08/01
Expected recruitment end date
2024-10-22, 1403/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating sperm parameters, DNA integrity, embryo cytokinetic and pregnancy rate from sperms selected by cumulus column compared to the control group in male

factor infertile couples.

Public title
Sperm selection by cumulus column
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertility couples with a male factor without varicocele diagnosis (at least one of the three sperm parameters outside the normal values defined by WHO) and a normal woman based on regular cycles, normal hysterosalpingogram, normal vaginal ultrasound, age under 38 years Estradiol level below 3000 and the presence of at least 3 follicles with a size > 14 on the trigger day Referring to the first or second cycle(s) of ICSI Having at least 6 mature MII oocytes for ICSI Male age less than 45 years
Exclusion criteria:
Male patients with severe male factor according to WHO criteria Frozen sperm sample Sperm sample obtained by aspiration or extraction from the testis HIV positive patients PCOS and endometriosis patients Patients at risk of OHSS
Age
To **38 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method is done individually and by statistical software
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patient, the clinical embryologist, and the gynecologist are considered blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences
Street address
Bouali Ave.Timsar Fallahi ST.Yazd
City
Yazd
Province
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Postal code
8916877391
Approval date
2023-06-27, 1402/04/06
Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.118

Health conditions studied

1

Description of health condition studied
Male infertility
ICD-10 code
N46
ICD-10 code description
Azoospermia NOS Oligospermia NOS

Primary outcomes

1

Description
chemical pregnancy
Timepoint
2 weeks after embryo transfer
Method of measurement
Beta hCG test

Secondary outcomes

1

Description
Differences in oocyte quality between individuals
Timepoint
The quality of oocyte is checked after puncture and before in vitro fertilization
Method of measurement
Grading based on standard criteria

Intervention groups

1

Description
Intervention group: The sperm selected for injection have passed through the cumulus column
Category
Treatment - Other

2

Description
Control group: The sperm selected for injection prepared with the density gradient method
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Science Institute, Research & clinical center for infertility, Shahid Sadoughi Uni
Full name of responsible person
Prof. Abbas Aflatoonian
Street address
Bouali Ave. Timsar Fallahi ST. Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Nasim Tabibnezhad
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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
Dr. Esmat Mangoli
Position
Assisted Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
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PhD students

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Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Maintaining and respecting the confidentiality of patient information

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
No - There is not 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
The results of the study will be published in the form of an article and the data file will be provided to the journal

When the data will become available and for how long
One year after the results are published

To whom data/document is available
researchers

Under which criteria data/document could be used
To write review studies and meta-analysis

From where data/document is obtainable
Principal Researcher

What processes are involved for a request to access data/document
Contact by email to the corresponding author and ensure the person's good faith

Comments