Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the pregnancy rate between two methods of tubal sperm perfusion with standard intrauterine sperm insemination in infertile patients referred to the infertility clinic

Protocol summary

Study aim

Determining and comparing the pregnancy rate between two methods of tubal sperm perfusion with standard intrauterine sperm insemination in infertile patients referred to the infertility clinic of Ali Ibn Abi Talib (AS) Zahedan Hospital in 2018

Design

Based on the day of the person's visit to the center, those who visit on an even day will enter the FSP group and those who visit on an odd day will enter the IUI group. The IUI group will be named A and the FSP group will be named B

Settings and conduct

The IUI group will be named A and the FSP group will be named B, and the outcome assessor and statistician will be blinded to the grouping. Then IUI and FSP treatment cycles will be implemented for patients of each group by the treatment team of the infertility center.

Participants/Inclusion and exclusion criteria

The inclusion criteria includes all women who refer to fertility centers of Ali Ibn Abi Talib Zahedan Hospital. Inclusion criteria include female age of 20 to 40 years, infertility of at least 10 years and body mass index (BMI) of less than 27 Kg/m2, hormone tests and hysterosalpingography (at least one normal fallopian tube). (moderate to severe oligospermia), bilateral obstruction in hysterosalpingography, very weak ovarian function, very weak ovarian reserve, the presence of simultaneous uterine anomalies and the presence of fallopian tube obstruction.

Intervention groups

FSP group: suspension inoculation of sperm with a volume of 4 cc into the uterus or fallopian tube IUI group: Sperm injection into the uterus

Main outcome variables

β-Hcg test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221203056697N1**
Registration date: **2023-01-02, 1401/10/12**
Registration timing: **retrospective**

Last update: **2023-01-02, 1401/10/12**
Update count: **0**

Registration date

2023-01-02, 1401/10/12

Registrant information

Name

Farahnaz Farzaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

farahnaz1826@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-21, 1398/06/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

2019-09-21, 1398/06/30

Actual recruitment end date

2022-09-21, 1401/06/30

Trial completion date

empty

Scientific title
Comparison of the pregnancy rate between two methods of tubal sperm perfusion with standard intrauterine sperm insemination in infertile patients referred to the infertility clinic

Public title
Comparison of pregnancy rate between two methods of tubal sperm perfusion with standard intrauterine sperm insemination

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
The age of the woman is 20 to 40 years Infertility less than 10 years Body mass index (BMI) less than 27 Kg/m2 Hysterosalpingography (at least one normal tube)
Exclusion criteria:
Male infertility (moderate to severe oligospermia) Bilateral obstruction in hysterosalpingography Ovaries with very poor function Very poor ovarian reserve The presence of uterine anomalies at the same time and the presence of obstruction of the uterine tubes

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The outcome assessor and data analyst were blinded to patient characteristics and patient grouping

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Persian Gulf Highway - University of Medical Sciences Campus Complex
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743175

Approval date
2020-02-16, 1398/11/27

Ethics committee reference number
IR.ZAUMS.REC.1399.048

Health conditions studied

1

Description of health condition studied
positive pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
positive pregnancy

Timepoint
Two weeks after treatment

Method of measurement
β-Hcg test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On days 3-7 of the monthly cycle after the ultrasound, 2 tablets of letrozole 2.5 mg (Iran hormone. Company) are prescribed daily for 5 nights. Then HMG gonadotropin or Gonal-f (Karma Company) was prescribed from day 7 to 10 cycles based on the patient's need in the amount of 3 to 4 pills daily. Next, 5 to 7 days after the last dose of letrozole, ultrasound is performed. When the follicles reach the size of 18 to 24 mm, HCG (Karma Company) is injected intramuscularly, and 36 to 48 hours later, the semen sample prepared by the gradient process with a volume of 4-6 cc is injected into the uterus through the IUI catheter.IUI group, which is intrauterine insemination of sperm

Category
Treatment - Other

2

Description

Intervention group: FSP group,which is Fallopian tube sperm perfusion

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abitaleb Hospital

Full name of responsible person

Farahnaz Farzaneh

Street address

Persian Gulf Highway - University of Medical Sciences Campus Complex

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Email

farahnaz1826@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

noor mohammad Bakhshani-Vice President of Research and Technology

Street address

Persian Gulf Highway - University of Medical Sciences Campus Complex

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Email

farahnaz1826@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Farahnaz Farzaneh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Persian Gulf Highway - University of Medical Sciences Campus Complex

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Contact

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Other areas of specialty/work

Gynecology and Obstetrics

Street address

Hemmat steet

City

Tehran

Province

Tehran

Postal code

9816743463

Phone

+98 21 6650 9283

Fax

Email

farahnaz1826@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Farahnaz Farzaneh

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Comparison of pregnancy rate between IUI and Fallopian tube Sperm Perfusion methods in patients with infertility referring to Ali ibn Abitaleb Hospital in Zahedan in 2019

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Request from the responsible author of the article

From where data/document is obtainable
farahnaz1826@yahoo.com

What processes are involved for a request to access data/document
request to farahnaz1826@yahoo.com

Comments