

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 Gonadotropin (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
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Persian Gulf Highway - University of Medical Sciences
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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
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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
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
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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