

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The efficacy and safety of intrauterine insemination (IUI) with different volumes of air during insemination catheter in infertile couples

Protocol summary

Study aim

Comparison between the success of clinical pregnancy in patients undergoing IUI with different volumes of air inside the catheter insemination performed during intrauterine insemination of sperm

Design

The controlled, parallel group, double blinded, randomized, phase II, on 3 groups consisted 90 patients and single center clinical trial. The randomization is performed using rand function. Two groups are considered as intervention and one group is considered as control. Patients were followed until two months after intervention.

Settings and conduct

The study will be performed at Imam Khomeini Hospital. Study will be Double blind, both the patient and the evaluator of the results will be unaware of the intervention. Hysterosalpingography is performed for all patients in all three groups for women and semen for men. All IUI cycles will be stimulated by ovarian gonadotropic stimulation from the second day of menstruation until the day of ovulation. At the stage of IUI, patients are divided into three groups according to the volume of air in the sperm injection catheter: volume of half a ml, 1 ml and no air. A soft catheter will be placed in the middle of the uterine cavity and a volume of semen will be injected in 15 seconds. After this time, perform pregnancy diagnostic tests (serum level b-hCG is recommended. And clinical pregnancy is performed according to ultrasound criteria to detect fetal heart rate 12 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with open fallopian tubes, FSH levels less than 12 IU/L, and normal sperms. Exclusion criteria: IUIs with donor sperm were excluded from the present study.

Intervention groups

At the stage of IUI, patients are divided into three groups according to the volume of air in the sperm injection

catheter: volume of half a ml, 1 ml and no air.

Main outcome variables

Pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201110049331N1**

Registration date: **2020-12-13, 1399/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-13, 1399/09/23**

Update count: **0**

Registration date

2020-12-13, 1399/09/23

Registrant information

Name

Roshan Nikbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6104

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nikbakht-r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy and safety of intrauterine insemination (IUI) with different volumes of air during insemination catheter in infertile couples

Public title
The air volume in intrauterine insemination

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with open fallopian tubes FSH levels less than 12 IU/L Normal sperms
Exclusion criteria:
IUIs with donor sperm were excluded from the present study

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **270**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple and individual randomization using random numbers were used. The random number are presented in sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants and evaluators were blinded from the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address

Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Central Building

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2018-10-06, 1397/07/14

Ethics committee reference number
IR.AJUMS.REC.1397.464

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Fertility rate

Timepoint
2 months after intervention

Method of measurement
Clinical pregnancy using sonography

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group 1: The volume of air in the catheter when injecting sperm in the first intervention group is 0.5 ml.

Category
Treatment - Devices

2

Description
Intervention group: The volume of air in the catheter when injecting sperm in the second intervention group is 1 ml

Category
Treatment - Devices

3

Description

Control group: The volume of air in the catheter when injecting sperm in the control group is zero.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Roshan Nikbakht

Street address

Azadegan Avn., Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research of Ahvaz Jundishapur 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

Ahvaz University of Medical Sciences

Full name of responsible person

Roshan Nikbakht

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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