Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of effectiveness and side effects of intrauterine insemination catheter with mandrel, a product of Slamtyar Hakim engineering company, in infertile couples

Protocol summary

Study aim

Determining the effectiveness and side effects of intrauterine insemination catheter with mandrel, a product of Slamtyar Hakim engineering company, in infertile couples

Design

A randomized Controlled Trial, with parallel groups, 60 patients , and without blinding. The patients randomly assigned to two groups using a random permutation block design

Settings and conduct

This is a concurrent parallel randomized controlled trial. This study will be performed in Shahid Beheshti Hospital (Isfahan) and without blinding. A total of 60 infertile couples will included in the study and randomly assigned into 2 groups of intervention and control. After intrauterine insemination, the first pregnancy test will be done about 2 weeks later to determine the status of chemical pregnancy. One month later, with an ultrasound and detection of fetal heartbeat, clinical pregnancy will be confirmed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having 2 to 3 follicles of suitable size, open tubes, acceptable sperm test for intrauterine insemination Exclusion criteria: Age over 42 years, bilateral tubular obstruction, couples with sperm concentration less than ten million spermatozoa per millilitre

Intervention groups

Control group: 30 patients, a catheter without mandrel, produced by Salamatyar Hakim engineering Company, will be used for intrauterine insemination of sperm. Intervention group: 30 patients, a catheter with mandrel, produced by Salamatyar Hakim engineering Company, will be used for intrauterine insemination of sperm.

Main outcome variables

Primary outcomes: Problem with catheter insertion, Need to Tenaculum, Need for cervical dilatation Secondary outcomes: Chemical pregnancy rate, Clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160703028756N6**
Registration date: **2021-10-13, 1400/07/21**
Registration timing: **retrospective**

Last update: **2021-10-13, 1400/07/21**
Update count: **0**

Registration date

2021-10-13, 1400/07/21

Registrant information

Name

Elham Naghshineh

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

naghshineh@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness and side effects of intrauterine insemination catheter with mandrel, a product of Slamtyar Hakim engineering company, in infertile couples

Public title

Evaluation of intrauterine insemination (IUI) catheter (Mandrel contain) in infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having 2 to 3 follicles of suitable size, open tubes acceptable sperm test for intrauterine insemination

Exclusion criteria:

Age over 42 years bilateral tubular obstruction couples with sperm concentration less than ten million spermatozoa per millilitre

Age

To **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning samples to groups is in the form of two-treatment permutation block design with quadruple blocks. Thus, the letter A is considered for the masstec catheter group with mandrel and the letter B for the catheter group without mandrel. Then we write all the permutation compounds of the letters A, A, B, B, which are 6 different compounds, then we choose a number from the digits 1 to 6. For example, if the number 2 is selected, it means that the first person in the intervention group, the next two people in the control group and the fourth person in the intervention group. This operation continues until the sample size reaches the quorum.

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 Isfahan University of Medical Sciences

Street address

Deputy of research and technology, Isfahan University Of Medical Sciences, Hezarjerib St.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.MUI.MED.REC.1400.158

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Problem with catheter insertion

Timepoint

At the time of intrauterine insemination

Method of measurement

Questionnaire

2

Description

Need to Tenaculum

Timepoint

At the time of intrauterine insemination

Method of measurement

Questionnaire

3

Description

Need for cervical dilatation

Timepoint

At the time of intrauterine insemination

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Chemical pregnancy rate

Timepoint

2 weeks after intrauterine insemination

Method of measurement

Human chorionic gonadotropin Test

2

Description

Clinical pregnancy rate

Timepoint

5 weeks after intrauterine insemination

Method of measurement

Sonography

Intervention groups

1

Description

Control group:In the control group, including 30 patients, the catheter without mandrel, produced by Salamatyar Hakim engineering Company, will be used for intrauterine insemination of sperm.

Category

Treatment - Devices

2

Description

Intervention group: In the intervention group, including 30 patients, the catheter with mandrel, produced by Salamatyar Hakim engineering Company, will be used for intrauterine insemination of sperm.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Elham Naghshineh

Street address

Shahid Beheshti Hospital, Motahari St, Felezi Bridge, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Isfahan University Of Medical Sciences, Hezarjerib St., Isfahan, Iran

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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

10

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

2

Sponsor

Name of organization / entity

Salamat Yar Hakim Engineering Co

Full name of responsible person

Sayyed Emran Emami

Street address

Building No. 20, Alley No. 3, South Malek Street, Eight Western Paradise

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sayyedemranemami@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Salamat Yar Hakim Engineering Co

Proportion provided by this source
90

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Poursina Hakim Digestive Diseases Research Center
Full name of responsible person
Fatemeh Maghool
Position
Researcher
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Person responsible for updating data

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

Informed Consent Form
Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

The study protocol, informed consent form, and clinical study report may be shared.

When the data will become available and for how long

Start Access time:4 months after the publication of results

To whom data/document is available

Our data will be available for researchers working in academic and scientific institutions as well as those working in the industry

Under which criteria data/document could be used

The applicant must clearly state the purpose of the requested documentation. Written consent is required for any use of the data.

From where data/document is obtainable

To receive documentation, send your request via the following website: Poursina.masstecmedical.com

What processes are involved for a request to access data/document

After submitting a request, it takes about 7 working days for the application to be received by the applicant.

Comments