

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of efficiency and side effects of intrauterine insemination (IUI) catheter, a product of Slamtyar Hakim Engineering company, in infertile couples

Protocol summary

Study aim

Determine the efficacy and side effects of intrauterine insemination (IUI) catheter, a product of Slamtyar Hakim Engineering company, in infertile couples

Design

This study is a randomized controlled trial (RCT), a parallel concurrent study. 60 infertile couples will enter this study and continuous sampling method based on the Inclusion and exclusion criteria will be used. The method of assigning samples to the groups is a randomized block design with two blocks of four blocks.

Settings and conduct

Place of study: Shahid Beheshti Hospital and Milad Hospital of Isfahan In this method, the controlled ovarian stimulation method will be used. All semen samples will be provided within 7-3 days of sexual absenteeism. After the seminal fluid is hydrated, sperm parameters are analyzed according to the World Health Organization (WHO) standards by computerized method. The sperm will be prepared and a small amount of the culture medium will enter the cervix and cavity in the sterile state. The first pregnancy test will be done about 2 weeks later to determine the chemical pregnancy. A month later, clinical pregnancy will be recorded by ultrasound and observation of heartbeat.

Participants/Inclusion and exclusion criteria

The requirement for IUI is to have 2 to 3 follicles of appropriate size, open tubes and acceptable sperm testing for IUI. Women older than 42 years of age, have a double-sided tubular obstruction problem and men with a sperm concentration of less than 10 million spermatozoa per milliliter are excluded.

Intervention groups

Sixty patients, including two groups of 30, who use IUI catheter ® masstec and the other group uses similar foreign product.

Main outcome variables

1- Occurrence of chemical pregnancy after IUI 2- Occurrence of Clinical pregnancy after IUI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160703028756N5**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **prospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

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

2019-01-05, 1397/10/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficiency and side effects of intrauterine insemination (IUI) catheter, a product of Slamtyar Hakim Engineering company, in infertile couples

Public title

Evaluation of efficiency and side effects of intrauterine insemination (IUI) catheter in infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having 2 to 3 follicles of the right size, Tubes open
Acceptable Sperm Test for IUI

Exclusion criteria:

Women older than 42 years Double-sided tubular obstruction
Couples with sperm concentration less than 10 million spermatozoa per ml

AgeTo **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

In this study, a continuous sampling method based on the criteria for entering and leaving the study is used. The method of assigning samples to the groups is a randomized block design with two blocks of four blocks. The letter A for the masstec catheter and the letter B for the PM IU catheter group are considered. Then write all the permutation combinations of the letters A, A, B, and B, which are six different combinations (AABB for digit 1, ABBA for digit 2 ...), then we select a digit from the digits 1 to 6. For example, if digit 2 is selected, its concept is that the first person in the intervention group is the next two in the control group and the fourth in the intervention group. Continue this until the sample size reaches to 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

خیابان هزار جریب

City

اصفهان

Province

Isfahan

Postal code

81746-73461

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.MUI.MED.REC.1397.115

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Problem with catheter insertion

Timepoint

At the time of IUI

Method of measurement

Questionnaire

2**Description**

Need to Tenaculum

Timepoint

At the time of IUI

Method of measurement

Questionnaire

3**Description**

Need for cervical dilatation

Timepoint

At the time of IUI

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Chemical pregnancy rate

Timepoint

2 weeks after IUI

Method of measurement

HCG Test

2

Description

Clinical pregnancy rate

Timepoint

5 weeks after IUI

Method of measurement

Sonography

Intervention groups

1

Description

In the control group, intrauterine insemination of the sperm will be performed by a catheter from France.

Category

Treatment - Devices

2

Description

Intervention group: In the intervention group, IUI is performed by the IUI catheter ® masstec (Salamat Yar Hakim, Iran).

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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2

Recruitment center

Name of recruitment center

Milad Hospital

Full name of responsible person

Ataollah Ghahiri

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Milad Hospital, Shahid Bakhshi Street, Janbazan Boulevard, Simin Threeway

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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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Grant name

Grant code / Reference number

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

No

Title of funding source

Salamat Yar Hakim Engineering Co

Proportion provided by this source

100

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

Sponsor**Name of organization / entity**

Salamat Yar Hakim Engineering Co

Full name of responsible person

Sayyed Emran Emami

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

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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

Salamat Yar Hakim Engineering Co

Proportion provided by this source

100

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

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Poursina Hakim Digestive Diseases Research Center

Full name of responsible person

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Position

Researcher

Latest degree

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Other areas of specialty/work

Physiology

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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

Yes - There is 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

Yes - There is 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 share.

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 request, any use of the data must be obtained by Written consent after correspondence.

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 4 working days for the application to be received by the applicant.

Comments