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
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
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
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
8184851153
Phone
+98 31 3236 7001
Email
dr.naghshineh@gmail.com

2

Recruitment center
Name of recruitment center
Milad Hospital
Full name of responsible person
Ataollah Ghahiri
Street address
Milad Hospital, Shahid Bakhshi Street, Janbazan Boulevard, Simin Threeway
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Isfahan
Province
Isfehan
Postal code
8179663467
Phone
+98 31 3777 4001
Email
ghahiri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University Of Medical Sciences, Hezarjerib St., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Phone
+98 31 3792 3060
Email
sh_haghjoo@med.mui.ac.ir
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

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

City
Isfahan

Province
Isfehan

Postal code
8154638871

Phone
+98 31 3273 4080

Email
sayyedemranemami@gmail.com

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

Street address
No. 12, Yas Block 8, Keshvari Complex, Third Abshar Ave.

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Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Fatemeh Maghool

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
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Email
fmaghool@gmail.com

Person responsible for updating data

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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Postal code
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Email
fmaghool@gmail.com

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