

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effect of two types of soft embryo transfer catheters PM Trans Set Mini CH3 and Kitazato on the results of IVF in infertile women: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of two types of soft embryo transfer catheters PM Trans Set Mini CH3 and Kitazato on the results of IVF in infertile women. Design: a single blind randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemeh Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age less than 40; (b) (having more than 3 fetuses; (c) having healthy uterine cavity. Exclusion criteria: (a) having high baseline FSH level; (b) having a history of difficult transfer; (c) having more than 6 times IVF cycle; (d) idiopathic infertility; (e) donated fetus; (f) frizzed fetus. Intervention group: Embryo transfer using soft catheter PM Trans Set Mini CH3. Control group: Embryo transfer using soft catheter Kitazato. Primary outcome: (a) assessing pregnancy through measuring β hcg titer 14 days after embryo transfer; (b) assessing pregnancy through transvaginal ultrasonography 4 weeks after embryo transfer. Secondary outcome: Assessing the need to Tenaculum by checking presence of blood or mucous on the head of catheter immediately after embryo transfer. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of catheters. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601049014N88**

Registration date: **2016-01-17, 1394/10/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two types of soft embryo transfer catheters PM Trans Set Mini CH3 and Kitazato on the results of IVF in infertile women: a single blind randomized clinical trial

Public title

Comparison of the effect of two types of soft embryo transfer catheters PM Trans Set Mini CH3 and Kitazato on the results of IVF in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age less than 40; (b) (having more than 3 fetuses; (c) having healthy uterine cavity.

Exclusion criteria: (a) having high baseline FSH level; (b) having a history of difficult transfer; (c) having more than 6 times IVF cycle; (d) idiopathic infertility; (e) donated fetus; (f) frizzed fetus.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of catheters. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.UMSHA.REC.1394.369

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

assessing pregnancy

Timepoint

titer14 days after embryo transfer

Method of measurement

through measuring β hcg

2

Description

assessing pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

through transvaginal ultrasonography

Secondary outcomes

1

Description

Assessing the need to Tenaculum

Timepoint

immediately after embryo transfer

Method of measurement

by checking presence of blood or mucous on the head of catheter

Intervention groups

1

Description

Embryo transfer using soft catheter PM Trans Set Mini CH3

Category

Treatment - Devices

2

Description

Embryo transfer using soft catheter Kitazato

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Hasan Bahrami

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Fatemieh Hospital

Full name of responsible person

Dr Hasan Bahrami

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Associate Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty