

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of endometrial scratch versus no scratch on pregnancy outcome in patients undergoing intrauterine insemination: a single blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of endometrial scratch versus no scratch on pregnancy outcome in patients undergoing intrauterine insemination.

Design

This is a single-blind randomized clinical trial, phase II, in which 300 eligible infertile women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergoing intrauterine insemination who will refer to ... Hospital during the study period will be enrolled into the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age of 18 to 40 years Infertility Body mass index less than or equal to 30 and greater than or equal to 18 Normal menstrual period Normal fallopian tube Exclusion criteria Hirsutism Autoimmune disease Endocrine disease Using cigarette or alcohol

Intervention groups

Intervention group: Endometrial scratch using Pipelle in the luteal phase and one week before intrauterine insemination Control group: Introducing cotton swab into the uterus without scratching in the luteal phase and one week before intrauterine insemination

Main outcome variables

Primary outcome: Assessing pregnancy three months after intervention using sonography.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201707129014N174**
Registration date: **2017-07-14, 1396/04/23**
Registration timing: **prospective**

Last update: **2018-02-12, 1396/11/23**

Update count: **1**

Registration date

2017-07-14, 1396/04/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of endometrial scratch versus no scratch on pregnancy outcome in patients undergoing intrauterine insemination: a single blind randomized clinical trial

Public title

The effect of endometrial scratch versus no scratch on pregnancy outcome in patients undergoing intrauterine insemination

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 40years Infertility Body mass index less than or equal to 30 and greater than or equal to 18 Normal mensural period Normal fallopian tube

Exclusion criteria:

Hirsutism Autoimmune disease Endocrine disease Using cigarette of alcohol

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Random assignment of the patients to the intervention and control groups using random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

Placebo

Not used

Assignment

Parallel

Other design features**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

Province

Hamadan

Postal code

6517838695

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

IR.UMSHA.REC.1396.153

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**

Assessing pregnancy

Timepoint

three months after intervention

Method of measurement

using sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Endometrial scratch using Pipelle in the luteal phase and one week before intrauterine insemination.

Category

Treatment - Surgery

2**Description**

Control group: Introducing cotton swab into the uterus without scratching in the luteal phase and one week before intrauterine insemination.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

Full name of responsible person

Dr Nesa Varmaghani

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3828 3939

Email

nvarmaghani@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences**Full name of responsible person**

Dr Saeid Bashirian

Street addressHamadan University of Medical Sciences, Shahid
Fahmideh Ave**City**

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice-chancellor for Research and Technology, Hamadan
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**

Fatemieh Hospital

Full name of responsible person

Dr Nesa Varmaghani

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3828 3939

Fax**Email**

nvarmaghani@gmail.com

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

Fatemieh Hospital

Full name of responsible person

Dr Nesa Varmaghani

Position

Resident of Gynecology

Latest degree

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Other areas of specialty/work

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Phone

+98 81 3828 3939

Fax**Email**

nvarmaghani@gmail.com

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

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

Web page address**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

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