Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 mensural period Normal fallopian tube Exclusion criteria Hirsutism Autoimmune disease Endocrine disease Using cigarette of 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

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Iran (Islamic Republic of)

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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.
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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
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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 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
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Person responsible for updating data

Contact
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Department of Epidemiology
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Dr Jalal Poorolajal
Position
Professor

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Ph.D.
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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
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