

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effect of local scratch of endometrium on the outcome of pregnancy in women with the previous failure of intrauterine insemination

Protocol summary

Study aim

Effect local scratch endometrium on outcome pregnancy in women with previous failure intrauterine insemination

Design

interventional study that was conducted on a non-randomized clinical trials in infertility center during 6 months. 336 patients 173 case, 163 control

Settings and conduct

336 women with infertile women in are divided into two groups of 173 and 163 patients. The group referring to infertility clinic on odd days, is consulted to participate in design and intervention, and after receiving informed consent on 8-9 days of menstrual cycle, endometrial scratch using Pipelle catheter is performed, but patients referring in even days, will be without any intervention and are divided into control group. On the 14th day after IUI, the biochemical pregnancy rate is measured with positive beta-test.

Participants/Inclusion and exclusion criteria

Infertility women with one or two history of failure in IUI or IO who are planning to have a pregnancy and are candidates for IUI. Inclusion criteria: Patients are candidates for induction ovulation and intrauterine insemination. Normalized thyroid and prolactin function tests. Age range 18 to 40 years. BMI < 30 kg/m², and 1 < AMH < 3.5, Having at least one healthy fallopian tube and normal uterine cavity. Normalized semen fluid or mild oligospermia. Exclusion criteria: No consent to participate in the study. Poor Response patients (AMH < 1 ng/dl) Disturbance thyroid function and high prolactin. Double blocked fallopian tubes or hydrosalpinx, and those with polycystic ovarian disease (PCOD)

Intervention groups

receiving or not receiving endometrial scratch using pipelle divided into two groups of control and scratch

Main outcome variables

Comparison of success rate of pregnancy in the two groups

General information

Reason for update

Change in the inclusion and exclusion criteria to increase accuracy in selected sample cases of study and change in the number of sample and change in the time of study due to the large number of samples and prolonged duration of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20180731040659N1**
Registration date: **2018-09-03, 1397/06/12**
Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **2**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Farzaneh Khastefekr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5631

Email address

farzanehkhastefekr@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-11-28, 1398/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Effect of local scratch of endometrium on the outcome of pregnancy in women with the previous failure of intrauterine insemination

Public title
Effect of local scratch of endometrium on the outcome of pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria of the study were:infertility women with one or two history of failure in IUI or IO who are planning to have a pregnancy and are candidates for IUI despite proper ovulation and primary and secondary infirtility with having at least one patent fallopian tube,women aged18_40years BMI<30kg/m2and1<AMH<3.5with normal thyroid and prolactin funtional tests.normal semen analysis,and mild oligospermia
Exclusion criteria:
Exclusion criteria,. No consent to participate in the study, Poor Response patients(AMH<1ng/dl) Disturbance of thyroid function and high prolactin, double blocked fallopian tubes or hydrosalpinx), People with polycystic ovary disease(PCOD)

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **336**

Randomization (investigator's opinion)
Not randomized

Randomization description
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,Dental Collage
Street address
Persian Goulf Blvd,Aliibn Abitalib Hospital
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Approval date
2018-06-17, 1397/03/27
Ethics committee reference number
IR.ZAUMS.REC.1397.144

Health conditions studied

1
Description of health condition studied
Infertility
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Pregnancy
Timepoint
On the 14th day after IUI, the biochemical pregnancy rate is measured
Method of measurement
Serum pregnancy test

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: on based receiving or no receiving endometrial scratch using paipel is divided
Category
Treatment - Devices

Recruitment centers

1
Recruitment center
Name of recruitment center
infertility clinic of Ali Ibn Abi Talib in Zahedan
Full name of responsible person
Farahnaz Farzaneh
Street address
Perian gulf ,Blvd.Ali Ebne abitaleb Hospital
City

Zahedan
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Postal code
9816743111
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+98 54 3329 5631
Email
Farahnaz1826@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noor Mohammad Bakhshani
Street address
Persian Gulf Blvd, Aliebnabitaleb Hospital
City
Zahedan
Province
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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
Zahedan 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
The University of Zahedan
Full name of responsible person
Farzaneh Khasteh Fekr
Position
Gynecology Assistant
Latest degree
Medical doctor
Other areas of specialty/work

Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of of medical science Zahedan
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Position
Infertility fellowship
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Infertility fellowship
Latest degree
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Other areas of specialty/work
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Phone

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Email

Farahnaz1826@yahoo.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

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