Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluating the effects of local endometrial injury on success of pregnancy rate in patients candidate for in vitro fertilization (IVF).

Protocol summary

Study aim

Evaluating the effects of local endometrial injury on the success rate of pregnancy in patents under invitro fertilization (IVF).

Design

Interventional clinical trial , sample size 324. Selection by list of clients and the availability and availability of entry conditions

Settings and conduct

A study on infertile women with at least one history of unsuccessful IVF referred to the Reproductive Clinic of Mahdieh Hospital in Tehran, whose endometrial thickness will be inappropriate. Patients will normally undergo IVF and ovulation and in vitro fertilization. Initial ultrasound will be performed before the intervention in the luteal phase. On the first to third day of the cycle, small scratches are made in different parts of the uterus using a pipette. On day 8-10 of the cycle, an ultrasound will be performed again. If thickness of more than 7 mm, while starting progesterone as a cyclogest suppository, the patient is introduced for embryo transfer to be done in two or three days. B-hCG titers were also checked 2 weeks after embryo transfer. Also, 5 weeks after the transfer, the presence of clinical pregnancy will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-40; Normal uterine cavity; Lack of OCP or GnRH reagent for FET ; abnormal endometrial wall diameter. Exclusion criteria: Intrauterine factors including fibroids; Endometrial and endometrial hyperplasia; Active vaginal and cervical infection; systemic disease

Intervention groups

intervention group:women referring to the infertility clinic, IVF candidates who have inappropriate endometrial thickness, who received the intervention of endometrial damage with papillae. control group:patients themselves before the intervention

Main outcome variables

Effect of endometrial abrasion on endometrial condition, β-hCG positivity ,and the presence of clinical pregnancy with ultrasound.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140224016705N11**
Registration date: **2021-11-05, 1400/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-05, 1400/08/14**
Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effects of local endometrial injury on success of pregnancy rate in patients candidate for in vitro fertilization (IVF).

Public title
Evaluating the effects of local endometrial injury on success of pregnancy rate in patients candidate for in vitro fertilization.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
History of infertility with a history of unsuccessful IVF candidate for in vitro fertilization Existence of inappropriate endometrial thickness based on ultrasound Age 40 years or less Do not use OCP or GnRH for FET in the previous cycle Appropriate quality of embryos for transfer
Exclusion criteria:
Vaginal or cervical active infection Endometrial Hyperplasia Existence of endometritis Presence of known intrauterine pathologies on ultrasound or hysteroscopy such as fibroids or myomas Asherman syndrome Uterine anomaly
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: **324**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti university of medical sciences, Arabi Ave, Yamen St, Chamran Highway, Tehran
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Approval date
2021-01-31, 1399/11/12
Ethics committee reference number
ir.sbmu.msp.rec.1399.650

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Existence of clinical pregnancy (formation of pregnancy sac and fetal heart) in IVF patient under the intervention of endometrial abrasion with papillae.
Timepoint
5 weeks after the transfer, transvaginal ultrasound will examine the presence of clinical pregnancy (formation of pregnancy sac and fetal heart).
Method of measurement
transvaginal ultrasound

2

Description
β-hCG positivity (greater than 10 mIU / mL)
Timepoint
B-hCG titer was checked 2 weeks after embryo transfer
Method of measurement
Using a laboratory-approved β-hCG test

3

Description
The effect of endometrial abrasion on endometrial condition
Timepoint
On day 8-10 of the cycle, an ultrasound will be performed again and the condition of the endometrium will be examined
Method of measurement
transvaginal ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes infertile women with at least one failed IVF history and re-candidate for IVF referred to the Reproductive Clinic of Mahdieh Hospital in Tehran, whose endometrial thickness is based on inappropriate ultrasound criteria (echogenic or thin view with a thickness of less than 5 mm) and in ultrasound or hysteroscopy of internal pathology They will not have a uterus such as a myoma or fibroid. Patients are routinely involved in the IVF process and ovulation and in vitro fertilization will be performed for each patient. The initial ultrasound will be done before the intervention in the luteal phase (about a week before the next period). Then, on the first to third day of the cycle, small blows were applied to different parts of the uterus using a pipette and small scratches were created. On day 8-10 of the cycle, ultrasound was performed again and the condition of the endometrium was examined. If there is a triple line view or a thickness of more than 7 mm, while starting progesterone as a cyclogest suppository, the patient is introduced for embryo transfer to be done in two or three days. B-hCG titers were also checked 2 weeks after embryo transfer. Also, 5 weeks after the transfer, the presence of clinical pregnancy (formation of pregnancy sac and fetal heart) will be examined by transvaginal ultrasound. Outcomes studied include the effect of endometrial abrasion on endometrial condition adaptation, β-hCG positivity (greater than 10 mIU / mL) and the presence of clinical pregnancy with ultrasound.

Category

Treatment - Devices

2

Description

Control group: Each patient is considered as a control group. In this way, each patient is classified as a control group according to the infertility conditions in terms of uterine endometrial diameter before the intervention. Conditions before and after endometrial ablation with papillae in terms of uterine diameter and fertility will be evaluated as case and control groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital Infertility Center

Full name of responsible person

Dr Zahra Heydar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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assistant professor
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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
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable