Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of electrotherapy in improving uterine blood supply in women with a history of repeated IVF implantation failure

Protocol summary

Study aim
Effect of pelvic electrotherapy in improving uterine artery blood flow in women with a history of RIF.

Design
A controlled, single-blind, randomized, clinical trial on 22 patients. For randomization, block randomization will be done using a secure, web-based randomization system with a 1:1 allocation ratio.

Settings and conduct
Infertile women referring to the Alzahra infertility clinic are visited by a gynecologist and infertility specialist between days one and three of the menstrual cycle. Transvaginal ultrasound was performed by an ultrasound specialist, and if they meet the inclusion criteria and do not meet the exclusion criteria, they will be included in the study with informed consent. The letter (PT) indicates the allocation in the pelvic electrotherapy intervention group and the letter (C) indicates the allocation of the conventional drug treatment control group.The laboratory expert and sonographer will be blinded to the intervention group allocation.

Participants/Inclusion and exclusion criteria
Infertile women who have referred to the infertility clinic of Al-Zahra Hospital for re-implantation through IVF. Entry requirements: age between 20 and 40 years, history of at least two failed transfers, embryo grade A or B.

Intervention groups
Pelvic electrotherapy intervention group (PT), conventional drug treatment control group (C). In both groups, conventional medical treatment including estrogen in the form of 2 mg estradiol tablets will start on the second day of the menstrual cycle. On the second day of the cycle, 2 tablets and from the third day of the cycle, 3 tablets of estradiol will be prescribed per day. From the sixth day, amilodipine will be started once a day for both groups. For the intervention group (PT), electrotherapy of the pelvis, monotherapy and pelvic floor exercises are performed.

Main outcome variables
successful pregnancy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230206057338N1**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date
2023-12-07, 1402/09/16

Registrant information
Name
Zahra Chakeri
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-26, 1402/09/05
Expected recruitment end date
2024-06-26, 1403/04/06
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of electrotherapy in improving uterine blood supply in women with a history of repeated IVF implantation failure

Public title
Investigating the effect of electrotherapy in improving uterine blood supply in women with a history of repeated IVF implantation failure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female Age between 20 and 40 years History of at least two failed transfers Embryo grade A or B

Exclusion criteria:
Having any of the cases of congenital anomaly of the uterus, fibroids or any intrauterine lesions, severe endometriosis, uterine myomas, uterine adenomyosis, ovarian cysts and antral follicles with sizes larger than 12 mm, severe ovulation disorder including prolonged oligoamenorrhea, premature ovarian failure and hypothalamic amenorrhea, suffering from any internal disease associated with blood flow disorders such as diabetes and dyslipidemia, smoking and alcohol consumption, special diets such as vegetarianism, autoimmune diseases, hypertension and coagulation disorders, intrauterine adhesions (Asherman syndrome)and other organic injuries, uterine dysplasia, mental illnesses, mental disorders, contraindications for estrogen therapy, anemia, hyperthyroidism, heart disease, liver disease, kidney disease, and other diseases that lead to a decrease in menstruation People whose embryos are not grade A or B after resuscitation or the thickness of the endometrium is less than 6 mm on the day of endometrial conversion,

Age
From **20 years** old to **40 days** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used for randomization. Central randomization will be performed on the web using a random faith system with a 1:1 feature ratio. The allocation sequence is created by the person who is not participating in the study process and using random numbers generated by The selection of blocks will continue until the division of 22 patients into two groups (electrotherapy intervention group (PT) and conventional drug treatment control group (C)).The selected blocks will be recorded as a consecutive sequence and a number from 1 to 22 will be assigned to each of the PT and C letters in the created sequence. According to this sequence, the people included in the study will be assigned to one of the two groups of electrotherapy (PT) or conventional drug treatment (C). Due to the unpredictability of the sequence created by the block randomization method, all researchers except the allocator will be unaware of the size and order of the blocks.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the study, it is impossible to blind the participants, the gynecologist and the therapist who applies the electrotherapy treatment. However, the laboratory technician and sonographer will be blinded to the intervention group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
No. 23, Nasr Ave., Golkar Blvd., Tabriz City

City
Tabriz

Province
East Azarbaijan

Postal code
5156937895

Approval date
2023-10-02, 1402/07/10

Ethics committee reference number
IR.TBZMED.REC.1402.491

Health conditions studied

1

Description of health condition studied
Infertility related to women with a history of at least two implantation failures (RIF).

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Primary outcome: successful pregnancyoutcomes of the research.
Timepoint
Before entering the study,12 weeks after implantation.
Method of measurement
To check a successful pregnancy, the implantation rate, the number of gestational sacs and the growth of the fetus until the 12th week of pregnancy will be recorded and analyzed and compared.

Secondary outcomes

1

Description
Arterial resistance index
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Examination of arterial resistance index is done using transvaginal ultrasound. To identify the state of uterine blood supply, the blood flow changes of the uterine arteries, arcuate artery and subendometrial vessels will be investigated in the follicular stage. Measurements will be reported independently for the right and left uterine arteries.

2

Description
Arterial pulsatility index
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Examination of arterial pulsatility index is done using transvaginal ultrasound. To identify the state of uterine blood supply, the blood flow changes of the uterine arteries, arcuate artery and subendometrial vessels will be investigated in the follicular stage. Measurements will be reported independently for the right and left uterine arteries.

3

Description
Peak systolic velocity
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Examination of peak systolic velocity is done using transvaginal ultrasound. To identify the state of uterine blood supply, the blood flow changes of the uterine arteries, arcuate artery and subendometrial vessels will be investigated in the follicular stage. Measurements will be reported independently for the right and left uterine arteries.

4

Description
End diastolic velocity
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Examination of end diastolic velocity is done using transvaginal ultrasound. To identify the state of uterine blood supply, the blood flow changes of the uterine arteries, arcuate artery and subendometrial vessels will be investigated in the follicular stage. Measurements will be reported independently for the right and left uterine arteries.

5

Description
Endometrial pattern
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Evaluation of the endometrial pattern is done using transvaginal ultrasound.

6

Description
Endometrial thickness
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
Evaluation of endometrial thickness is done using transvaginal ultrasound.

7

Description
FSH hormone level
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
The level of FSH hormones is obtained by performing a blood test.

8

Description
Sexual performance index
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
The FSFI index is used to measure women's sexual performance in six different areas of sexual desire, arousal, fluidity, orgasm, satisfaction and pain.

9

Description
The level of depression
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
The BDI questionnaire is used to check the level of depression.

10

Description
Quality of Life
Timepoint
Before entering the study, after drug and electrotherapy intervention (after 1 Month)
Method of measurement
the SQOL-F questionnaire will be used to check the quality of sexual life in women.

Intervention groups

1

Description
Intervention group: Pelvic electrotherapy. They receive the usual medical treatment. From the 6th to the 12th day of the cycle, oral amlodipine is prescribed once a day at a dose of 5 mg. Intervention group: pelvic electrotherapy. For electrotherapy, electric current with internal frequency of 150 Hz, closed frequency of 2 Hz, pulse duration of 250 milliseconds and variable amplitude between 0 and 90 will be used for 30 minutes. Electrical stimulation will be done using a vaginal electrode. The patient is placed in a supine position with bent knees. The pelvic floor physiotherapist pours the required amount of lubricating gel on the vaginal electrode and inserts the electrode into the vagina. Then the device is turned on with the mentioned settings and the intensity of the current is increased to the tolerance threshold of the patient. For tecartherapy, heat is provided using capacitive electrodes with a frequency of 300 kHz for 20 minutes. For this, we first cover the abdomen and sacrum using a layer of special cream for the device. Then, a passive metal electrode is placed in the sacrum area and the single pole active electrode with a diameter of 0.5 cm is moved around the uterus and ovaries by the pelvic floor physiotherapist. Pelvic floor exercises are divided into four phases. The proprioceptive phase in the first week includes proprioceptive exercises to adequately understand the exercises and perform fast and slow contractions. The simple phase in the second week aims to improve the control of fast and slow contractions during simple performance activities. The advanced phase in the third week, in which functional exercises with a greater range are performed. The strength phase is done in the last week to increase the strength of the contraction. In all sessions, contractions will be performed for slow and fast fibers.
Category
Rehabilitation

2

Description
Control group: Conventional drug therapy. They receive only the usual medical treatment. From the 6th to the 12th day of the cycle, once a day amlodipine is administered orally at a dose of 5 mg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic of Al-Zahra Educational Hospital
Full name of responsible person
Zahra Chakeri
Street address
Al-Zahra Educational and Treatment Center (S)., Baghshamal Crossroad ., South Army Street ., Tabriz City .,East Azarbaijan
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Sponsors / Funding sources

1

Sponsor
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Grant name
Tabriz University of Medical Sciences Student Research Committee grant project
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
No
Title of funding source
Tabriz University of Medical Sciences Student Research Committee grant project
Proportion provided by this source
50
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
Tabriz University of Medical Sciences
Full name of responsible person
Zahra Chakeri
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The information related to the main and secondary outcome, the method of electrotherapy after deidentifying people, informed consent form and completed questionnaires, statistical analysis and spss file, study protocol, codes used in the analysis, data

dictionary can be subscribed.

When the data will become available and for how long

The access period starts 6 months after the publication of the relevant articles

To whom data/document is available

Permission to receive data or other study documents will be granted only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If you request more information to refer to the article or use it for further research in the field of electrotherapy and infertility

From where data/document is obtainable

By sending a message to the e-mail address of Zahra Chakeri at the following address: z.chakeri@gmail.com

What processes are involved for a request to access data/document

Sending a message by the requester, checking the message, correspondence to find out the original request, finding the requested items and sending to the requester. The process takes a maximum of one month

Comments