Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

the effecacy of biofeedback and neuromuscular stimulation in Increasing the thickness of endometrium more than 7 millimeter with vaginal sonography in women 24 t0 45 years old that uterin thin and less of 7 millimeter endometrium despite received estrogen and progestron during embryo transfer

Protocol summary

Study aim
Crises fertility at fetal transfer with crises uterine Endometrial that is important factor in fertility
Design
TWO arm parallel group randomised trial with blinded postoperative care and outcom assessment
Settings and conduct
From infertility injuries andwant embryo transfer to Sarem hospital ,a midwife accepts randomly individual who control and control the conditions of the plan
Participants/Inclusion and exclusion criteria
Woman's with aged 24 to45 years and 2 time canseled. transfer reason endometrial uterine less 7 milimeter without chronic disease
Intervention groups
Infertility woman
Main outcome variables
Increased endometrial thickness, increased blood flow to the uterus and fertility

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190212042685N1**
Registration date: **2019-07-03, 1398/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-03, 1398/04/12**
Update count: **0**
Registration date
2019-07-03, 1398/04/12

Registrant information
Name
Mehri Nejat
Name of organization / entity
Sarem Hospital
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-06-06, 1398/03/16
Expected recruitment end date
2020-06-05, 1399/03/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
the effecacy of biofeedback and neuromuscular stimulation in Increasing the thickness of endometrium more than 7 millimeter with vaginal sonography in women 24 t0 45 years old that uterin thin and less of 7 millimeter endometrium despite received estrogen and progestron during embryo transfer

Public title
biofeedback and neuromuscular stimulation in infertility

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
24_45 Canceled 2 time. Emberyo transfer to cause thin thickness uterine There are 2 fetal
Exclusion criteria:
Endometriosis Diabetic Epileptic Cardiovascular disease Anomaly uterine and vagan Bleeding Choronic Mental disorder Mental retard Infection Chronic skin disorder
Age
From **24 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **1**
One female
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Accident. Blind ,the midwife of adolescents from 24 to 45 year_old women with a condio al design including two consecutive embryo transfer sequences due to thinness of thoracic endometrium and two_part freeze with out chronic disease were randomly divided into control and international groups without any knowledge of the clients.Each group in the control group ,only the homonthrapy is performed according to the previous procedure and biofeedback and neuromuscular stimulation.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients don't information about control and intervatuion groups both groups receive an endometrial treatment by a gynecologist and the midwife divides the admission into the control and intermediate group
Placebo
Not used
Assignment
Single
Other design features
Biofeedback and. neuromuscular stimulation is physiotherapy unit with vaginal prop cause increase plvic blood supply

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics committee on Bit medical Research
Street address
BlokA,13th.Floor.,Ministry of Health and Medical education, South of South falamak-Ghoss-Theran
City
tehran
Province
Tehran
Postal code
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Approval date
2019-02-02, 1397/11/13
Ethics committee reference number
IR.IUMS.REC.۱۳۹۷.۹۸۴

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Increasing the thickness of the uterin endometer over 7 millimeter
Timepoint
3,6,12 day
Method of measurement
Vaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: women aged 24 to 45 without chronic diseases with 2 times canceling of embryo transfer dup to thickness of uterine endometrium
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Sarem hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Sarem hospital
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Agapeh clinic
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Agapehclinic
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Mehri nejat
Position
Specialist
Latest degree
Specialist
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

All of data 's without name and phone numbers ,analysis and conclusion will provide pdf and archive at Agapehclinic and sarem hospital

When the data will become available and for how long

Without limitation

To whom data/document is available

Gynecologistsand midwives or physician

Under which criteria data/document could be used

People 's want to try in the same projects or treatment infertility patients

From where data/document is obtainable

Dr.Mehri nejat Sepantareshadi@gmail.com 00989122561447

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

Gynecologist and midwife or physician Degree of education also have knowledge about biofeedback and infertility patients

Comments

This treatment help infertility and very useful