

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

the efficacy of biofeedback and neuromuscular stimulation in Increasing the thickness of endometrium more than 7 millimeter with vaginal sonography in women 24 to 45 years old that uterine thin and less than 7 millimeter endometrium despite received estrogen and progesterone 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 outcome assessment

Settings and conduct

From infertility injuries and want 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 to 45 years and 2 time canceled. transfer reason endometrial uterine less than 7 millimeter 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)

Phone

+98 21 4604 0339

Email address

sepantareshadi@gmail.com

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 efficacy of biofeedback and neuromuscular stimulation in Increasing the thickness of endometrium more than 7 millimeter with vaginal sonography in women 24 to 45 years old that uterine thin and less than 7 millimeter endometrium despite received estrogen and progesterone during embryo transfer

Public title

biofeedback and neuromuscular stimulation in infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

24_45 Canceled 2 time. Embryo 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

۱۴۷۱۴۷۲۳۴۱

Approval date

2019-02-02, 1397/11/13

Ethics committee reference number

IR.IUMS.REC.1۳۹۷.۹۸۴

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
Mehri nejat
Street address
Sarem hospital,fazeh1-Ekbatan
City
tehran
Province
Tehran
Postal code
1476612325
Phone
+98 21 4463 3284
Email
sepantarehadi@gmail.com

2

Recruitment center
Name of recruitment center
Cent sexual disease Agapeh
Full name of responsible person
Mehri nejat
Street address
N.1,narges ale, Shiraz North sth. -molasadera-vanac
City
tehran
Province
Tehran
Postal code
۱۴۷۲۳۶۵۷۸۹
Phone
+98 21 8804 0283
Email
sepantarehadi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sarem hospital
Full name of responsible person
Abotaleb sareh
Street address
Sarem hospital,fazed 1,Ekbatan
City
tehran
Province
Tehran
Postal code
۱۴۷۲۳۴۵۶۹۸
Phone
+98 21 4469 7012
Email
sepantarehadi@gmail.com
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
Full name of responsible person
Mehri nejat
Position
Specialist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
N.37,hidari moghadam st.,ponak squeeze.
City
tehran
Province
Tehran
Postal code
۱۴۷۶۶۱۲۳۲۵
Phone
+98 21 4604 0331
Email
sepantarehadi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Agapehclinic
Full name of responsible person
Mehrinejat
Position
Specialist
Latest degree
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Other areas of specialty/work
Psychiatrics
Street address
N.37,hidari moghadam st., ponak square.
City
tehran
Province
Tehran
Postal code

۱۳۷۶۶۱۲۳۲۵

Phone

+98 46040339

Email

sepantareshadi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Agapehclinic

Full name of responsible person

Mehrinejat

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

N.37, hidari moghadam sth.,ponak square.

City

tehran

Province

Tehran

Postal code

۱۳۷۶۶۱۲۳۲۵

Phone

+98 21 4604 0339

Email

sepantareshadi@gmail.com

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 sareh 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