

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Assessing the effects of acupressure on anxiety, self-efficacy, and pregnancy rate in the infertile women undergoing intra cytoplasmic sperm insemination (ICSI) and description of their perception and experience of this treatment

Protocol summary

Summary

The aim of this study is to determine the effect of acupressure on anxiety, self-efficacy and pregnancy in infertile women undergoing intracytoplasmic sperm insemination (ICSI) and explain their understanding and experience from this treatment. This mix method study consisted of two stages that the first part is a clinical trial. The sample size is 144 infertile women. Inclusion criteria include female infertility, primary infertility, undergoing treatment ICSI, no history of mental illness and, age between 20 to 45 years. Exclusion criteria are: stressful events during study for participants, no participation in more than 2 of intervention sessions. Then, the Beck Anxiety Inventory (Beck) is completed by them. People with severe anxiety are excluded. The questionnaires consisted of infertility self-efficacy and social support perceived questions are completed by people who entered study. The subjects are randomly divided into three groups: sham and real acupressure and control groups. Patients receive acupressure treatment three times a week for 4 weeks with ICSI. The control group will receive only ICSI treatments. Acupressure is performed until a day before the embryo transfer. Again after intervention, questionnaires are completed in three groups. An employee outside the research team will complete the questionnaires with aim of blinding or masking the study group assignment. Data analysis is done by consulting statistics. Finally, β HCG hormone assay is performed to determine pregnancy in three groups, 15 days after embryo transfer. In this study, major variables are including anxiety, self-efficacy and pregnancy rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506072924N2**

Registration date: **2015-12-15, 1394/09/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-15, 1394/09/24

Registrant information

Name

Maryam Hassanzadeh Bashtian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, mashhad University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effects of acupressure on anxiety, self-efficacy, and pregnancy rate in the infertile women undergoing intra cytoplasmic sperm insemination (ICSI) and description of their perception and experience of this treatment

Public title

Effect of acupressure on th self-efficacy, anxiety and pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian native, female infertility, primary infertility, undergoing treatment ICSI, no history of mental illness, age between 20 to 45 years, do not take anti-anxiety and anti-depressant medications, no history of use of acupressure, and acupressure is not performed during this study for other diseases. Exclusion criteria: stressful events during study for participants, abnormal uterine cavity, severe anxiety, no participation in more than 2 of intervention sessions, without desire to continue to participate in the study

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In the groups allocation is used from Fleiss randomization table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad University of Medical Sciences

Street address

Across 18, Daneshgah street, Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.MUMS.REC.1394.313

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

female infertility

Primary outcomes

1

Description

Anxiety. self-efficacy. social support

Timepoint

Before intervention. Immediately after intervention end

Method of measurement

Beck anxiety inventory. infertility self-efficacy questionnaire Cousineau. social support questionnaire Zimet

Secondary outcomes

1

Description

pregnancy rate

Timepoint

Almost one month after intervention end

Method of measurement

B HcG test

Intervention groups

1

Description

Acupressure is done by a researcher for the subjects at the HT7 and PC6 points. Each point is pressed in the both hands for three minutes. Acupressure is done three times in the week for 4 weeks.

Category

Other

2

Description

Sham group: In the sham group, the misplaced points that are in two cm from main areas are used for acupressure.

Category

Other

3**Description**

control group not receive any intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Milad IVF center

Full name of responsible person

Maryam Hassanzadeh Bashtian

Street address

School of Nursing and midwifery, Doktora intersection, Daneshgah Street.

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

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Voice research.Mashhad University of Medical Sciences

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Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty