

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The Effects of Acupuncture on Infertility-related Stress and In Vitro Fertilization (IVF) Outcomes

Protocol summary

Study aim

Considering the high prevalence of infertility-related concerns and limited studies on the efficiency of acupuncture in infertility-related stress and IVF outcomes, we conduct this study to determine whether acupuncture affects infertility-related stress in infertile patients, refer to Omme-Leila Infertility Clinic in Bandar Abbas, Iran..

Design

Two parallel groups with randomized trial with pretest-posttest and evaluation.

Settings and conduct

This quasi-experimental study had a pretest-posttest control-group design. The statistical population included all infertile patients in the age range of 25-45 years under IVF treatment at Omme-Leila Infertility Clinic during 2018. A total of 120 patients were randomly divided into either the case or control group (60 patients per group) via convenience sampling. Data were collected by distributing questionnaires among patients before and after acupuncture and 35 minutes before embryo transfer

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study are all female patients referring to the Bandar Abbas Omme-leila clinic between 25-45 years old . Patients under 25 years old and over 45 years old and rare diseases patients are not include from this study.

Intervention groups

The data were collected by distributing Newton questionnaire in control group 35 minutes before embryo transfer.

Main outcome variables

This study impacts acupuncture on 1- social concerns; 2- sexual concerns; 3- relationship concerns; 4- need for parenting; 5- childless lifestyle; referring to Bandar Abbas Omme- Leila Infertility Clinic for IVF.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200202046336N1**

Registration date: **2020-03-08, 1398/12/18**

Registration timing: **retrospective**

Last update: **2020-03-08, 1398/12/18**

Update count: **0**

Registration date

2020-03-08, 1398/12/18

Registrant information

Name

Kobra Haji Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3367 0255

Email address

ph_alizadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-01-21, 1397/11/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

The Effects of Acupuncture on Infertility-related Stress and In Vitro Fertilization (IVF) Outcomes

Public title

The effect of acupuncture on reducing infertility stress

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All infertile women between 25-45 years old, who were referred to Omme-Leila Infertility Clinic in Bandar Abbas, Iran, in 2018.

Exclusion criteria:

People with rare diseases are not include in this study,

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **133**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Our considered sample size is 120 (with 60 people in each group). Block randomization method will be designed by using randomization list and Individuals will be placed in the 6-block blocks in the order of days. 60patients are in intervention group (5 groups of 8-12 patients as entering in to the study) and 60 patients in control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hormozgan University of Medical Sciences

Street address

Islamic Azad University of Bandar Abbas,Daneshgah BLV, Golshahr

City

Bandar Abbas

Province

Hormozgan

Postal code

7915899143

Approval date

2018-10-14, 1397/07/22

Ethics committee reference number

IR.HUMS.REC.1397.221

Health conditions studied**1****Description of health condition studied**

This study investigates the impact of acupuncture on infertility stress

ICD-10 code

Z31.2

ICD-10 code description

in vitro fertilization

Primary outcomes**1****Description**

The primary outcome variable in this study is the rate of stress reduction in infertile patients (25-45 years old) referred to Omme-Leila clinic .

Timepoint

Acupuncture is performed 35 minutes before embryo transfer.

Method of measurement

Newton Infertility Stress Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Patients complete the Newton questionnaire after training, then they receive acupuncture treatment services, and after that patients complete the questionnaire again. After 35 minutes the embryo is transferred.

Category

Treatment - Other

2**Description**

Control group:35 minutes before embryo transfer, the control group completed the Newton questionnaire.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omme-leila Infertility Clinic

Full name of responsible person

Zahra Khashavi

Street address

Omme-leila Hospital, Omme-leila Infertility Clinic,
Nayband e Shomali, Bandar Abbas, Hormozgan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandar Abbas Islamic Azad University

Full name of responsible person

Alireza Saybani

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BLV, Golshahr

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Web page address

<http://iauba.ac.ir>

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

Yes

Title of funding source

Bandar Abbas Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Kobra Haji Alizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

M.A Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

Omme-leila Infertility Clinic

Full name of responsible person

Zahra Khashavi

Position

M.D

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only primary outcome measure can be share

When the data will become available and for how long

starting in 2021

To whom data/document is available

This data will only be available to academic researchers

Under which criteria data/document could be used

I have no other conditions.

From where data/document is obtainable

Applicants can email az.joodaki@gmail.com to receive data from this study.

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

If you have a letter of intent from research centers or universities you can request information.

Comments