

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A sham-controlled trial of acupuncture on preoperative anxiety in pregnant women candidate for elective cesarean section

Protocol summary

Summary

The aim of the study: Comparison of the effect of acupuncture on preoperative anxiety in pregnant women candidate for elective cesarean section. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be randomly allocated into intervention and control group. Randomization will be performed using random block sizes of 4. The study is randomized, single-center. Inclusion criteria: Pregnant women candidate for elective cesarean section. Exclusion criteria: Opium addiction; history of chronic disease. Sample size: 100 patients are participated in the study with 50 patients in each group. The intervention used in the study: 5-7 sterile acupuncture needle with sizes 13-15 or 25 . Primary outcome: Rate of anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053034237N1**

Registration date: **2017-06-05, 1396/03/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-05, 1396/03/15

Registrant information

Name

Mehrasa Heydari

Name of organization / entity

Shahroud University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A sham-controlled trial of acupuncture on preoperative anxiety in pregnant women candidate for elective cesarean section

Public title

The effect of acupuncture on preoperative anxiety in pregnant women candidate for elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women candidate for elective cesarean section Exclusion criteria: Opium addiction; history of chronic disease

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be performed using random block sizes of 4

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Shahrood

Street address

Islamic Azad University of Shahrood, Tehran Blvd, Shahrood

City

Shahrood

Postal code

3613773955

Approval date

2017-03-09, 1395/12/19

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.22

Health conditions studied

1

Description of health condition studied

anxiety before cesarean section

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after the intervention

Method of measurement

Amsterdam Anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inserting 5-7 sterile acupuncture needle with sizes 13-15 or 25 on true acupoints and maintaining them for 25-30 minutes

Category

Treatment - Drugs

2

Description

Control group: Inserting 5-7 sterile acupuncture needle with sizes 13-15 or 25 on superficially not in real acupuncture points and maintaining them 25-30

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

khatam Alanbia Hospital of Shahrood

Full name of responsible person

Yousef Kolukhi

Street address

khatam Alanbia Hospital, Tehran Blvd, Shahrood

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person

Sahebali Manafi

Street address

Islamic Azad University of Shahrood, Tehran Blvd

City

Shahrood

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 and Technology, Islamic Azad University of Shahrood

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

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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