Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

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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
Shahroud
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 questionnier

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
Shahroud

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 Shahroud, Tehran Blvd
City
Shahroud
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