

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 2026

### The effect of acupressure on anxiety before cesarean section and nausea, vomiting and pain after cesarean section in woman admitted to hospital

#### Protocol summary

##### Study aim

The effect of acupressure on anxiety before cesarean section and pain, nausea and vomiting after cesarean section in women admitted to Vali Asr Hospital in 1396

##### Design

In this study, 60 patients undergoing cesarean section surgery were selected randomly. Participants were randomly assigned to two groups of control and intervention and each participant was given a code.

##### Settings and conduct

The present study is a randomized, single blind randomized clinical trial. This study is done at Valiasr Hospital in Fasa, Iran. The individual in the placebo group will not be aware of the ineffectiveness of the acupressure point. Acupressure points used in the pre-surgery Yintang and HE-7 points. Also, the points used after surgery are the ST-36 and the LI-4 point.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: have no skin problems at the point of acupressure, no use of sedative and stimulant drugs such as alcohol, no use of anti-nausea medicines after surgery. Exclusion criteria: spinal anesthesia

##### Intervention groups

The groups in this study are divided into two groups of 30 person. The intervention group receive acupressure at the HE-7 and Yintang Point. The control group also receive acupressure at an ineffective point.

##### Main outcome variables

Anxiety is evaluated before surgery and after the surgery, the pain and nausea and vomiting of the patients are evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171015036784N3**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **retrospective**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

##### Registration date

2018-01-29, 1396/11/09

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 913 669 4977

###### Email address

fo.abadi@fums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-11, 1396/09/20

##### Expected recruitment end date

2018-01-20, 1396/10/30

##### Actual recruitment start date

2017-12-13, 1396/09/22

##### Actual recruitment end date

2018-01-25, 1396/11/05

##### Trial completion date

empty

##### Scientific title

The effect of acupressure on anxiety before cesarean section and nausea, vomiting and pain after cesarean section in woman admitted to hospital

##### Public title

Effect of acupressure on anxiety, nausea, vomiting and pain

##### Purpose

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
 Having Iranian nationality Having no specific problem at the site of acupressure (no wounds, burns, cysts, abscess) No use of sedatives, analgesics or anxiety drugs before surgery. Being alert before surgery. No an emergency condition before surgery. No history of mental illness. No history of using acupressure before surgery No history of drug or alcohol addiction. Not having physical problems (vision, hearing, mental) No previous history of nausea and vomiting after surgery No receive analgesic and anti-nausea medicine after surgery. Having an age range of 18 to 45 years Use of general anesthesia during surgery

**Exclusion criteria:**  
 The patient's unwillingness to continue cooperation in research Cancellation of the patient's cesarean section during the study or occurrence of any problem during the study (chest pain and shortness of breath) Using anti-nausea and vomiting drugs after surgery Spinal anesthesia History of liver disease

**Age**  
 From **18 years** old to **45 years** old

**Gender**  
 Female

**Phase**  
 N/A

**Groups that have been masked**

- Participant

**Sample size**  
 Target sample size: **60**  
 Actual sample size reached: **60**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Block randomization method consists of 4-part blocks. In each block, two person are in the control group and two in the intervention group. Before surgery and during sampling, the samples are matched in two groups of control and intervention in terms of age before thirty years, after thirty years and history of Cesarean section.

**Blinding (investigator's opinion)**  
 Single blinded

**Blinding description**  
 Before surgery, the control group receive an acupressure at an inaccurate point. The control group do not know about the point being ineffective.

**Placebo**  
 Used

**Assignment**  
 Parallel

**Other design features**

**Secondary Ids**  
 empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
 Ethics committee of Fasa University of Medical Sciences

**Street address**  
 Valiasr Hospital, Ebn Sina Square

**City**  
 Fasa

**Province**  
 Fars

**Postal code**  
 8668874616

**Approval date**  
 2017-12-11, 1396/09/20

**Ethics committee reference number**  
 IR.FUMS.REC.1396.276

**Health conditions studied**

**1**

**Description of health condition studied**  
 Anxiety

**ICD-10 code**  
 F06.4

**ICD-10 code description**  
 Anxiety disorder due to known physiological condition

**2**

**Description of health condition studied**  
 Pain

**ICD-10 code**  
 G89.18

**ICD-10 code description**  
 Other acute postprocedural pain

**3**

**Description of health condition studied**  
 Nausea and vomiting

**ICD-10 code**  
 R11

**ICD-10 code description**  
 Nausea and vomiting

**Primary outcomes**

**1**

**Description**  
 Reduce anxiety

**Timepoint**  
 One hour before transfer to the operating room, and immediately after the intervention.

**Method of measurement**  
 Spielberger's Standard Spell Checker Questionnaire (measurement of anxiety will be low to high).

## 2

### **Description**

Reduce pain

### **Timepoint**

The first turn of the acupuncture is one hour after the surgery and the second intervention is also three hours after the first intervention.

### **Method of measurement**

Visual Analogue Scale

## 3

### **Description**

Reduce nausea and vomiting

### **Timepoint**

The first turn of the acupuncture is one hour after the surgery and the second intervention is also three hours after the first intervention. The intervention period will be ten minutes at two st-36, li-4 points.

### **Method of measurement**

A questionnaire for assessing nausea and vomiting is a Rhodes index.

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: Before surgery, they receive acupuncture in two points, Yintang and HE-7, at the same time for five minutes. After surgery, st-36 and li-4 acupuncture for ten minutes.

### **Category**

Treatment - Other

## 2

### **Description**

Control group: Before surgery, the control group receive acupuncture for five minutes at Ineffective point. After surgery, the control group will not receive acupuncture at any point.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Vali Asr hospital

#### **Full name of responsible person**

Faezeh Abadi

#### **Street address**

Valiasr Hospital, Ebn Sina Square

#### **City**

Fasa

### **Province**

Fars

### **Postal code**

7461686688

### **Phone**

+98 71 5335 0994

### **Email**

faeze.abadi@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Fasa University of Medical Sciences

#### **Full name of responsible person**

Faezeh Abadi

#### **Street address**

Ebn Sina Square, Fasa University Of Medical Science

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### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Fasa University of Medical Sciences

### **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**

Fasa University of Medical Sciences

#### **Full name of responsible person**

Faezeh Abadi

#### **Position**

Academic instructor

#### **Latest degree**

Master

#### **Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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 the original outcome information can be released.

**When the data will become available and for how long**

Starting the access period from 1399

**To whom data/document is available**

Study data will be available to academic researchers.

**Under which criteria data/document could be used**

Only if the source of data usage is mentioned is allowed.

**From where data/document is obtainable**

Email us at: faeze.abadi@yahoo.com

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

After sending the email to the address, the author tries to provide the applicant with the required information within a maximum period of one month if requested.

**Comments**