

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of Ondansetron and PC6 acupressure point on postoperative nausea and vomiting in patients, undergone elective cesarean section in 2016; a randomized clinical trial

#### Protocol summary

##### Summary

The aim of this randomized triple blind research is to compare Ondansetron and acupressure effects on nausea and vomiting after elective cesarean. Inclusion criteria are including the age range of 18 to 45 years, elective cesarean, being NPO 8 to 12 hours before surgery, lack of digestive and cardiovascular diseases, not taking immunosuppressive drugs, stability of hemodynamic condition, and American Society of Anesthesiologists classes I and II patients. Exclusion criteria are including lack of desire to cooperation in the study, change in surgery trend, outbreak of uncommon and unexpected problem, severe nausea and vomiting according to anesthesiologist's diagnosis, and the weight more than 100 kg and less than 50 kg. The research population is female patients after elective cesarean in a total of 120 people. In this study, Ondansetron and acupressure would be used after clamping umbilical cord. First, the patients will be classified into 2 equal groups with randomized block allocation, 4 mg of Ondansetron will be prescribed for Ondansetron group, and a bracelet will be fastened without any pressure, 2 mg of distilled water will be prescribed for acupressure group, and a bracelet will be fastened with pressure. During the surgery, the continuous monitoring of heart rate will be performed. The severity of nausea, outbreak and number of episodes of vomiting will be measured and compared during surgery, recovery, and 6 hours after surgery in female surgical ward.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201603155596N3**

Registration date: **2016-04-12, 1395/01/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-04-12, 1395/01/24

##### Registrant information

###### Name

Nasrin Galehdar

###### Name of organization / entity

Lorestan University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66142099714

###### Email address

galehdar.n@lums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy of research and technology of Lorestan University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Ondansetron and PC6 acupressure point on postoperative nausea and vomiting in patients, undergone elective cesarean section in 2016; a randomized clinical trial

## Public title

Comparative effect of Ondansetron and acupressure on nausea and vomiting

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: elective cesarean; being NPO 8 to 12 hours before surgery; being NPO 6 hours after surgery; lack of symptomatic digestive disease; lack of motion sickness; lack of dizziness; lack of cardiovascular disease; lack of pulmonary disease; lack of middle ear disease; lack of diabetes; lack of infectious disease; lack of fever; lack of hypertension; lack of lateral surgery except for cesarean; lack of carpal tunnel syndrome; not taking alcohol; not taking immunosuppressive drugs; lack of long or unusual bleeding; lack of hemoglobin level less than 10 mg/dl; not receiving drugs except for antibiotics and analgesics in form of Diclofenac suppository daily 6 hours after surgery; American Society of Anesthesiologists classes I and II patients; patients with mild diseases without any performance limitation; patients with controlled disease; controlled diabetes or hypertension without systemic effects; smoking without chronic obstructive pulmonary disease; mild obesity; pregnant women aged 18 to 45 years with 38 to 40 weeks pregnant; exclusion criteria: lack of desire to continue cooperation in each step of research; change in surgery trend such as needing to general anesthesia; outbreak of any problem and uncommon and unexpected complication; severe nausea and vomiting according to anesthesiologist's diagnosis; emergency cesarean; having lateral surgery except for cesarean; the weight more than 100 kg and less than 50 kg.

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Lorestan University of Medical Sciences

#### Street address

Khorramabad, Kilometer 5 of Khorramabad-Tehran road, Lorestan University of Medical Sciences, Pardis complex, Deputy of research and technology

#### City

Khorramabad

#### Postal code

#### Approval date

2016-03-08, 1394/12/18

#### Ethics committee reference number

LUMS.REC.1394.46

## Health conditions studied

## 1

### Description of health condition studied

Nausea and vomiting

### ICD-10 code

r11

### ICD-10 code description

Nausea and vomiting

## Primary outcomes

## 1

### Description

Nausea

### Timepoint

During the surgery, recovery, and in female surgical ward till 6 hours after the surgery

### Method of measurement

Using checklist, asking questions and visual scale criteria

## Secondary outcomes

## 1

### Description

Outbreak of vomiting

### Timepoint

During the surgery, recovery, and in female surgical ward till 6 hours after the surgery

### Method of measurement

Using checklist, asking questions and visual scale criteria

## 2

### Description

Number of episodes of vomiting

### Timepoint

During the surgery, recovery, and in female surgical ward till 6 hours after the surgery

### Method of measurement

Using checklist, asking questions and visual scale criteria

## Intervention groups

### 1

#### Description

Prescribing Ondansetron in elective cesarean patients after clamping umbilical cord

#### Category

Prevention

### 2

#### Description

Applying acupressure in elective cesarean patients after clamping umbilical cord

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Asali Hospital

##### Full name of responsible person

Dr. Nasrin Galehdar

##### Street address

##### City

Khorramabad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Full name of responsible person

Dr. Morovat Taheri Kalani

##### Street address

Khorramabad, Kilometer 5 of Khorramabad-Tehran road, Lorestan University of Medical Sciences, Pardis complex, Deputy of research and technology

##### City

Khorramabad

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Lorestan 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

Lorestan University of Medical Sciences

##### Full name of responsible person

Dr. Nasrin Galehdar

##### Position

Faculty member

##### Other areas of specialty/work

##### Street address

Khorramabad, Kilometer 5 of Khorramabad-Tehran road, Lorestan University of Medical Sciences, Pardis complex, Deputy of research and technology

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+98 66 3340 9971

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##### Email

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Full name of responsible person

Dr. Nasrin Galehdar

##### Position

Ph.D of Nursing

##### Other areas of specialty/work

##### Street address

Khorramabad, Kilometer 5 of Khorramabad-Tehran road, Lorestan University of Medical Sciences, Pardis complex, Deputy of research and technology

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Abouzar Mohammadi

##### Position

BSc. of Surgical Technology  
**Other areas of specialty/work**  
**Street address**  
Kashan, Ghotb-e-ravandi blvd  
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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*