

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

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Name of organization / entity

Lorestan University of Medical Sciences and Health Services

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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

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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

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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