

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Assessment of Pyridoxine (Vitamin B6) effects on the Nausea and Vomiting Rates in Patients candidate for Elective Cesarean Section

Protocol summary

Study aim

Effect of vitamin B6 on rate of nausea and vomiting in patients after elective cesarean section

Design

Clinical trials with control group, parallel group, double blind, randomized

Settings and conduct

This study is done to evaluate the effect of vitamin B6 on pregnant women who are candidates for cesarean section who are referred to Besat Hospital in Sanandaj. The study is randomized and double blind.

Participants/Inclusion and exclusion criteria

Pregnant women candidate for elective cesarean section
Inclusion criteria: 1- Fasting for 8 hours before surgery 2- candidate for elective cesarean section 3. Patient's full health of the digestive tract 4- Filling out the consent form and willingness to participate in the study 5. Being monogamous
Exclusion criteria: 1. Contraindications for spinal anesthesia 2. History of vertigo and vomiting during pregnancy 3. Patients who have used anti-nausea and vomiting before surgery 4. Get psychotropic drugs 5. Patients with a BMI greater than 28 6- Patients with pre-eclampsia, eclampsia, hypertension, oesophageal hernia, gastroesophageal reflux disease 7. Patients with diabetes

Intervention groups

1. Group 1, 25 mg of vitamin B6 in combination with 500 ml of normal saline is given 20 minutes before surgery.
2- Group 2, 50 mg of vitamin B6 in combination with 500 ml of normal saline is injected 20 minutes before surgery.
3. Group 3, 100 mg of vitamin B6 in combination with 500 ml of normal saline is injected 20 minutes before surgery.
4. Group 4 (Control) 500 ml of normal saline is injected 20 minutes before surgery.

Main outcome variables

The incidence of nausea and vomiting, the amount of anti-emetic drugs Consumption, the patient's hospitalization time and the incidence of pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037910N1**

Registration date: **2019-04-19, 1398/01/30**

Registration timing: **prospective**

Last update: **2019-04-19, 1398/01/30**

Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

Arvin Barzanji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3334 2561

Email address

arvin.barzanji1988@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Pyridoxine (Vitamin B6) effects on the Nausea and Vomiting Rates in Patients candidate for Elective Cesarean Section

Public title

Vitamin B6 in elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Fasting for 8 hours before surgery candidate for elective cesarean section Patient's full health of the digestive tract Being monogamous Filling out the consent form and willingness to participate in the study

Exclusion criteria:

Patients with diabetes Contraindications for spinal anesthesia or Conversion of spinal anesthesia into general anesthesia during surgery History of vertigo and vomiting during pregnancy Patients who have used anti-emetic drugs before surgery Get psychotropic or opioid drugs Patients with a BMI greater than 28 Patients with pre-eclampsia, eclampsia, hypertension, oesophageal hernia, gastroesophageal reflux disease

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced (permuted) block randomization(four random blocks). In each block, 4 patients are randomly assigned random codes A1, A2, A3 and B, and according to the corresponding code, they receive the dose and the desired drug or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The normal saline serum containing medicine or placebo is prepared and coded by a nurse who is not aware of the study process. The prescriber and collaborator, who completes the relevant assessments and completes the questionnaire, is not aware of the drug or placebo received by the patient. After completion of the data collection work, analyzes will be carried out based on the relevant codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Blvd.

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2018-06-26, 1397/04/05

Ethics committee reference number

IR.MUK.REC.1397.086

Health conditions studied

1

Description of health condition studied

Nausea and vomiting after surgery in cesarean section with spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Primary outcome: nausea and vomiting

Timepoint

Nausea and vomiting are investigated during surgery and recovery time, and 2, 4, 6, 12, 18, and 24 hours after surgery.

Method of measurement

The BARF method is based on the BARF ruler and according to the smileys, scoring is done. 2. Qualitative method (Likert scoring criterion)

Secondary outcomes

1

Description

The amount of anti-emetic drugs

Timepoint

In the first 24 hours after surgery

Method of measurement

Dosage and frequency of administration

2

Description

Intensity of pain

Timepoint

Intensity of pain is investigated during recovery time, 2, 4, 6, 12, 18, and 24 hours after surgery.

Method of measurement

Pain is measured using the visual analog scale.

3

Description

The length of the recovery period

Timepoint

In the recovery period

Method of measurement

Based on time (hours)

4

Description

The length of hospitalization

Timepoint

Patient admission period

Method of measurement

Based on time (day)

Intervention groups

1

Description

Intervention group: Prescribing vitamin B6 : 25 mg, 20 minutes before surgery (group 1)

Category

Treatment - Drugs

2

Description

Intervention group: Prescribing vitamin B6 : 50 mg, 20 minutes before surgery (group 2)

Category

Treatment - Drugs

3

Description

Intervention group: Prescribing vitamin B6 : 100 mg, 20 minutes before surgery (group 3)

Category

Treatment - Drugs

4

Description

Control group: In the control group, 500 ml of normal saline solution will be infused 20 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Seyed Arvin Barzanji

Street address

Merdoux Crossroads- Keshavarz Street -Azadi Square

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Email

besathospital@muk.ac.ir

Web page address

<http://muk.ac.ir/Muk/Hospitals/Besat.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

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Web page address

<http://muk.ac.ir/Muk/ViceChancelleries/first.aspx>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Seyed Arvin Barzanji

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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