

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of ginger extract on the incidence and severity of nausea and vomiting after cesarean section under spinal anesthesia

#### Protocol summary

##### Summary

The Goal of study is determine the effect of ginger extract on the incidence and severity of nausea and vomiting after cesarean section under spinal anesthesia. In this randomized clinical trial, 92 pregnant women who underwent cesarean section under spinal anesthesia were divided in two groups of control and intervention. Patients should be alert, have class 1 and class 2 of America Society of Anesthesiology (ASA) without any infection or bleeding and ulcers in the area of spinal and without any relative or absolute limitation for spinal anesthesia. The intervention group received 25 drops of ginger extract in 30 cc of water and the control group only received 30 cc of water one hour before surgery. The incidence and severity of nausea and vomiting during the surgery, 2 and 4 hours after the surgery was assessed by self report scale

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042719359N3**

Registration date: **2016-05-13, 1395/02/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-13, 1395/02/24

##### Registrant information

###### Name

Hossein Zeraati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 58 3151 0000

##### Email address

zeraatih911@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, North Khorasan University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### 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

The effect of ginger extract on the incidence and severity of nausea and vomiting after cesarean section under spinal anesthesia

##### Public title

The effect of ginger extract on the incidence and severity of nausea and vomiting

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: patients should be alert; having class 1 and class 2 of America Society of Anesthesiology (ASA) score; without any infection or bleeding and ulcers in the area of spinal; without any relative or absolute limitation for spinal anesthesia Exclusion criteria: the patient who referred for cesarean section with a drop in the fetal heart rate, placenta detachment, and placenta previa; the patients who weigh more than 90 kg; diabetics; with underlying gastrointestinal disease; those who had used anti-nausea and anti-vomiting drugs in pre-operative 24

hours before the surgery; those who were not fasting; those with middle ear disease; those who had more than 20% of baseline drop in blood pressure after spinal anesthesia; the patients with gestational hypertension; history of pelvic surgery except caesarean section; history of nausea and vomiting during the past 24 hours

#### **Age**

From **15 years** old to **45 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **92**

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

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

###### **Street address**

Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd

###### **City**

Bojnurd

###### **Postal code**

##### **Approval date**

2012-10-27, 1391/08/06

##### **Ethics committee reference number**

91/60/1700

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Pregnancy

##### **ICD-10 code**

O08

##### **ICD-10 code description**

normal pregnancy

### **Primary outcomes**

#### **1**

##### **Description**

Severity of nausea

##### **Timepoint**

During the surgery, 2 hour after the surgery, 4 hour after the surgery

##### **Method of measurement**

self-report scale

#### **2**

##### **Description**

Severity of vomiting

##### **Timepoint**

During the surgery, 2 hour after the surgery, 4 hour after the surgery

##### **Method of measurement**

self-report scale

### **Secondary outcomes**

#### **1**

##### **Description**

The incidence of nausea and vomiting

##### **Timepoint**

During the surgery, 2 hour after the surgery, 4 hour after the surgery

##### **Method of measurement**

Self-report scale

### **Intervention groups**

#### **1**

##### **Description**

In the intervention group, 25 drops of oral drops containing gingerextract was poured in 30 cc of tap water in a glass and was given to the patients one hour before surgery

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

The control group received 30 cc of tap water in a glass one hour before surgery

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Bentolhoda Hospital

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

Javad Shahinfar  
**Street address**  
ZAyeshgah Ave, Bojnurd, Iran  
**City**  
Bojnurd

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor for Research, North Khorasan  
University of Medical Sciences

**Full name of responsible person**  
Alireza Golshan

**Street address**  
Vice Chancellor for Research, North Khorasan  
University of Medical Sciences, Bojnurd, Iran

**City**  
Bojnurd

#### 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, North Khorasan 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**  
North Khorasan University of Medical Sciences

**Full name of responsible person**  
Javad Shahinfar

**Position**  
Instructor

#### Other areas of specialty/work

**Street address**  
School of Nursing and Midwifery, Bojnurd, Iran

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#### Web page address

## Person responsible for scientific inquiries

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**Full name of responsible person**  
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**Position**  
Specialist

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## Person responsible for updating data

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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*