

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The influence of oral Ginger before operation on nausea and vomiting after cataract surgery under general anesthesia: A double-blind placebo-controlled randomized clinical trial.

#### Protocol summary

##### Summary

This study is conducted in order to determinate the influence of ginger orally on pain, nausea and vomiting after cataract surgery under general anesthesia. The study is done in Phase II clinical trials and single-center, double-blind. The study population is volunteer's cataract surgery patients in Tohid Hospital in Sanandaj. Based on inclusion criteria and attrition rate 129 participants are Purposefully selected. Randomization will be done using sealed envelopes and Participants are randomly allocated into two interventions and one placebo-control groups. Inclusion criteria included; surgical candidates; volunteered to participate in the study; lack of underlying chronic medical conditions; lack of nausea and vomiting; under general anesthetic with a specific drug. Exclusion criteria included cancel surgery, Patient's withdrawal from the research, cancel surgery and unpredicted events during surgery such as cardiac arrest or patient's death. In the first intervention group, the patients were given two capsules each of them 500 mg ginger at 6 a.m. before the operation. As of the second group, they were given two capsules each of them 500 mg ginger at 10 p.m. and 6 a.m. before the operation. In the control group, they were given a placebo capsule similar to capsules each of them 500 mg ginger at 6 a.m. before the operation. Based on Visual Analog Scale (VAS) as standard tool; severity of pain and nausea are recorded from zero to ten up to six hours after surgery. Incidences of pain, nausea and vomiting are recorded in the information sheet.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062122853N1**  
Registration date: **2016-08-18, 1395/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-18, 1395/05/28

##### Registrant information

###### Name

Simin Nazarian

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3366 4645

###### Email address

nazarian.simin@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

##### Expected recruitment start date

2015-06-15, 1394/03/25

##### Expected recruitment end date

2016-03-18, 1394/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The influence of oral Ginger before operation on nausea and vomiting after cataract surgery under general

anesthesia: A double-blind placebo-controlled randomized clinical trial.

#### Public title

The influence of oral Ginger on nausea and vomiting after cataract surgery

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria included; surgical candidates; volunteered to participate in the study; lack of underlying medical conditions (diabetes, chronic respiratory disease, chronic heart disease, kidney disorders, liver kidney disorders, kidney disorders, dementia, Alzheimer's disease and other acute or chronic disorders);Lack of preoperative nausea and vomiting; is to using general anesthesia with a specific drugs including propofol or thiopental. Exclusion criteria included Patient's withdrawal from the research, cancel surgery, and unpredicted events during surgery such as cardiac arrest or patient's death

#### Age

No age limit

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **129**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Randomization is done using sealed envelopes

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethic committee of Kurdistan University of Medical Sciences

#### Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Pasdaran street, Sanandaj, postal code:13446-66177

#### City

Sanandaj

#### Postal code

6617713446

#### Approval date

2015-01-19, 1393/10/29

#### Ethics committee reference number

IR.MUK.REC.93.132

## Health conditions studied

### 1

#### Description of health condition studied

cataract

#### ICD-10 code

H25.9

#### ICD-10 code description

Combined forms of senile cataract

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

From the moment of admission to recovery up to six hours after surgery. At the moment of admission to the ward after surgery and at 2, 4, and 6 hours after admission to the ward.

#### Method of measurement

Incidences of pain are recorded in the information sheet. Based on Visual Analog Scale (VAS) as standard tool; severity of pain is rated from zero to ten.

### 2

#### Description

nausea

#### Timepoint

From the moment of admission to recovery up to six hours after surgery. At the moment of admission to the ward after surgery and at 2, 4, and 6 hours after admission to the ward.

#### Method of measurement

Incidences of nausea are recorded in the information sheet. Based on Visual Analog Scale (VAS) as standard tool; severity of nausea is rated from zero to ten.

### 3

#### Description

vomiting

#### Timepoint

From the moment of admission to recovery up to six

hours after surgery. At the moment of admission to the ward after surgery and at 2, 4, and 6 hours after admission to the ward.

#### Method of measurement

Incidence of vomiting is recorded in the information sheet.

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Intervention group 2: the patients were given two capsules each of them 500 mg ginger at 10 p.m. and 6 a.m. before the operation.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: the patients were given a placebo capsule similar to capsules each of them 500 mg ginger at 6 a.m. before the operation.

#### Category

Treatment - Drugs

### 3

#### Description

intervention group1: the patients were given two capsules each of them 500 mg ginger at 6 a.m. before the operation

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tohid Hospital

##### Full name of responsible person

Simin Nazarian

##### Street address

Tohid Hospital, Tohid Street, Sanandaj

##### City

Sanandaj

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research and technology of Kurdistan University of Medical Sciences

##### Full name of responsible person

Farzin Rezaee

##### Street address

Vice Chancellor for research and technology of Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj, code:66177-13446

##### City

Sanandaj

#### 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 and technology of Kurdistan 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

Kurdistan University of medical sciences

##### Full name of responsible person

Simin Nazarian

##### Position

Faculty member/MS.C

##### Other areas of specialty/work

##### Street address

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##### Web page address

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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ph.D/Assistant professor

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## Person responsible for updating data

### Contact

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Assistant professor/ph.D

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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*