

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Effect of isopropyl alcohol nasal inhalation and intravenous ondansetron versus placebo on nausea and vomiting in patients with head trauma: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of isopropyl alcohol nasal inhalation and intravenous ondansetron versus placebo on nausea and vomiting in patients with head trauma

##### Design

This is a randomized clinical trial, phase II, in which 228 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with head trauma who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 80 years Mild head trauma (GCS of 14 to 15) Exclusion criteria: Severe trauma to other parts of the body Hypersensitivity to isopropyl alcohol nasal inhalation and ondansetron Inhalation disorder Mental disorder

##### Intervention groups

Intervention group 1: Inhalation of the saturated pad with 70% isopropyl alcohol for one minute at most 3 times in 2 minutes intervals Intervention group 2: Injection of intravenous ondansetron 0.1 mg/kg once Control group: Inhalation of the saturated pad with normal saline for one minute at most 3 times in 2 minutes intervals

##### Main outcome variables

Primary outcome: Assessing the severity of nausea and vomiting Secondary outcome: Assessing the severity of headache

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N271**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **retrospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

##### Registration date

2019-04-28, 1398/02/08

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-25, 1397/10/04

##### Expected recruitment end date

2019-03-03, 1397/12/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of isopropyl alcohol nasal inhalation and

intravenous ondansetron versus placebo on nausea and vomiting in patients with head trauma: a randomized clinical trial

#### Public title

Effect of isopropyl alcohol nasal inhalation and intravenous ondansetron versus placebo on nausea and vomiting in patients with head trauma

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age of 20 to 80 years Mild head trauma (GCS of 14 to 15) Nausea and vomiting

##### Exclusion criteria:

Severe trauma to other parts of the body Hypersensitivity to isopropyl alcohol nasal inhalation and ondansetron Inhalation disorder Mental disorder

#### Age

From **12 years** old to **80 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **228**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

#### 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 Hamadan University of Medical

Sciences

#### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2018-06-09, 1397/03/19

#### Ethics committee reference number

IR.UMSHA.REC.1397.159

### 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

Assessing the severity of nausea and vomiting

##### Timepoint

Before the intervention and at 2 and 4 and 6 and 10 minutes after the intervention

##### Method of measurement

Using visual analog scale (VAS)

### Secondary outcomes

#### 1

##### Description

Assessing the severity of headache

##### Timepoint

Before the intervention and at 2 and 4 and 6 and 10 minutes after the intervention

##### Method of measurement

Using visual analog scale (VAS)

### Intervention groups

#### 1

##### Description

Intervention group 1: Inhalation of saturated pad with 70% isopropyl alcohol for one minute at most 3 times in 2 minutes intervals

##### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: Injection of intravenous ondansetron 0.1 mg/kg once

### Category

Treatment - Drugs

## 3

### Description

Control group: Inhalation of saturated pad with normal saline for one minute at most 3 times in 2 minutes intervals

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital in Hamadan City

##### Full name of responsible person

Dr Mohammad Saleh Rasooli

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3364 0030

##### Email

rasooli117@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

hamadan

##### Province

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##### Postal code

6517838695

##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

##### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Saleh Rasooli

##### Position

Resident of Emergency Medicine

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Besat Hospital, Shahed Square

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##### Email

rasouls1@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Rasoul Salimi

##### Position

Emergency Medicine Specialist

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Emergency Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave**City**

Hamadan

**Province**

Hamadan

**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