

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)

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+98 81 1838 0090

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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

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Province

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6517838695

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+98 81 3364 0030

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Rasoul Salimi

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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

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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