

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 III, in which 228 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible head trauma patients who will refer to Besat Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 12 to 80 years; Light head trauma; GCS 14 to 15; Having nausea and vomiting; Exclusion criteria: Severe trauma to other parts of the body; Patients with sensitivity to isopropyl alcohol inhalation or Ondansetron; Inhalation disorder; Mental disorder

Intervention groups

Intervention group 1: Inhalation of pad impregnated with isopropyl alcohol 70% for one minute at a maximum of 3 times at 2 minutes intervals Intervention group 2: Intravenous injection of Ondansetron 0.1 mg/kg single dose. Control group: Inhalation of pad impregnated with normal saline for one minute at a maximum of 3 times at 2 minutes intervals

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N225**

Registration date: **2018-06-21, 1397/03/31**

Registration timing: **prospective**

Last update: **2018-06-21, 1397/03/31**

Update count: **0**

Registration date

2018-06-21, 1397/03/31

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-21, 1398/03/31

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 12 to 80 years Light head trauma GCS 14 to 15 Having nausea and vomiting

Exclusion criteria:

Severe trauma to other parts of the body Patients with sensitivity to isopropyl alcohol inhalation or Ondansetron Inhalation disorder Mental disorder

Age

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

Gender

Both

Phase

3

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

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

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Province

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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

Head trauma

ICD-10 code

G44.3

ICD-10 code description

Post-traumatic headache

Primary outcomes

1

Description

Assessing the severity of nausea and vomiting

Timepoint

Before intervention and 2, 4, 6, and 10 min after intervention

Method of measurement

Using visual analog scale (VAS)

Secondary outcomes

1

Description

Assessing the severity of headache

Timepoint

Before intervention and 2, 4, 6, and 10 min after intervention

Method of measurement

Using visual analog scale (VAS)

Intervention groups

1

Description

Intervention group 1: Inhalation of pad impregnated with isopropyl alcohol 70% for one minute at a maximum of 3 times at 2 minutes intervals

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous injection of Ondansetron 0.1 mg/kg single dose.

Category

Treatment - Drugs

3

Description

Control group: Inhalation of pad impregnated with normal saline for one minute at a maximum of 3 times at 2 minutes intervals

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Fatemeh Gholami Goodarzi

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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 Fatemeh Gholami Goodarzi

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Dr Jalal Poorolajal

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Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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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