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)
Phone
+98 81 1838 0090
Email address
poorolajal@umsha.ac.ir

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
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
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
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
f.gholamigudarzi@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
Hamadan
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 Fatemeh Gholami Goodarzi
Position
Resident of Emergency Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
f.gholamigudarzi@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
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
rasoulsl@yahoo.com

Person responsible for updating data

poorolajal@umsha.ac.ir

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

Postal code
6517838695

Phone
+98 81 3838 0090

Email

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