Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Adding Intravenous Midazolam to Apotel®in Treatment of Patients with Primary Headache Referred to Emergency Department

Protocol summary

Summary

1) Objectives: This research will be accomplished with the purpose of the effect of Adding Intravenous Midazolam to Apotel® in Treatment of Patients with Primary Headache Referred to Emergency Department 2) Design: 120 patients with primary headache will be divided two groups [Apotel plus Midazolam (group 1), Apotel (group 2)] with use Random Allocation Software. 3) Setting and conduct: After obtain the informed consent, severity of patient's headache, will be registered with using NAS. Then patient will be treated based on group number (1 or 2). 4) Participants including major eligibility criteria: inclusion criteria: All 18-65 years old patients with primary headache (Migraine or tension). Exclusion criteria: Sensitivity to used medicine, secondary type headache, vomiting, pregnancy, loss of consciousness, hepatic failure, breast-feeding, renal failure, psychotic disorder, get a medicine before arriving to emergency ward, dissatisfaction to participate to study. 5) Intervention: Type of treatment used in two groups are different. In group one Apotel plus Midazolam, and in group two Apotel will be used. 6) Main outcome measures variables: Duration of pain relief will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013112592N3**
Registration date: **2016-08-18, 1395/05/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-18, 1395/05/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Adding Intravenous Midazolam to Apotel®in Treatment of Patients with Primary Headache Referred to Emergency Department

Public title

Effect of adding sedative agent to analgesics for headache treatment

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: All 18-65 years old patients with primary headache (Migraine or tension). Exclusion criteria: Sensitivity to used medicine, secondary type

headache, vomiting, pregnancy, loss of consciousness, hepatic failure, breast-feeding, renal failure, psychotic disorder, get a medicine before arriving to emergency ward, dissatisfaction to participate to study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.TBZMED.REC.1395.325

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.1, G44

ICD-10 code description

migraine and other headache syndromes

Primary outcomes

1

Description

Duration of pain relief

Timepoint

The time between medicine prescription and pain releif

Method of measurement

With stopwatch

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

After the end of treatment, we will ask from patient about satisfaction of treatment

Method of measurement

Visual Analog Scale. This scale contains 1-10 scores that score 1 shows dissatisfaction and score 10 show excellent satisfaction

Intervention groups

1

Description

Intervention group 1: In this group, Midazolam (1cc, 5 mg, Darou pakhsh, Tehran, IR Iran) 0.02 mg/kg plus Apotel (1 gr, 6.7 cc, cobel darou, Tehran, IR Iran) 15 mg/kg (up to 1 gr) will be used intravenously.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, Apotel (1 gr, 6.7 cc, cobel darou, Tehran, IR Iran) 15 mg/kg (up to 1 gr) will be used intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Farzad Rahmani

Street address

Azadi Avenue, between Maralan and Hafez.

City

Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammadreza Rashidi
Street address
Golgasht Street, Tabriz University of Medical Sciences
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

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Web page address

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