

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effective comparison of Apotel versus Morphine in reducing of post pure head trauma headache

Protocol summary

Summary

Post Trauma Headache syndrome is one of several symptoms after trauma. So patients can experience the pain of somatic or psychological, or be the plaintiff. Various studies have been done on the effects of different drugs. Considering that Opioids in trauma patients can have adverse effects on the respiratory system. It can also affect the patient's vital signs, so the aim of the study on the use of intravenous acetaminophen in patients with head trauma and traumatic headache, in base of length and level of becoming symptom free and shot outcome (24 hours). GCS15 head trauma patients who has pure headache, age between 18 to 65 years and GCS=15 enrolled to this study, patients who is older than 65 or younger than 18, addiction to Opioids and GCS=14 or lower will excluded. Patients will divided in two groups randomly; according to last studies, each group will have 30 patients. For control group, 0.1 mg/kg Morphin will be infused and for case group 1gr Apotel will be diluted in 100 cc Normal saline and infused in 10 minutes. Before treatment, Headache will be assessed with numeric pain scale and after treatment and 24 hours later also with the same scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204127327N2**
Registration date: **2012-05-26, 1391/03/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-26, 1391/03/06

Registrant information

Name

Samad Shams Vahdati

Name of organization / entity

Tabriz University of Medical Scinces

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effective comparison of Apotel versus Morphine in reducing of post pure head trauma headache

Public title

Effective comparison of Apotel versus Morphine in reducing of post pure head trauma headache

Purpose

Treatment

Inclusion/Exclusion criteria

All patients with head trauma will be enrolled after obtaining the neurosurgery service examination result that there is no pathologic findings. Patients who have GCS14 or less or are older than 65 or age under 18 years

old are excluded
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Tabriz University of Medical Sciences Ethics
Committee
Street address
Golgasht street
City
Tabriz
Postal code
Approval date
2012-01-13, 1390/10/23
Ethics committee reference number
5/4/10392

Health conditions studied

1
Description of health condition studied
Traumatic headache
ICD-10 code
g44.3
ICD-10 code description
Chronic post-traumatic headache

Primary outcomes

1
Description

Headache
Timepoint
one week
Method of measurement
Numeric pain scale

Secondary outcomes

1
Description
Hypotension
Timepoint
10min
Method of measurement
Barometer

2
Description
Hypoxemia
Timepoint
10 min
Method of measurement
puls oximetry

Intervention groups

1
Description
In intervention group, 1 gr Apotel will be diluted in 100 cc
normal saline and be infused in 10 minutes
Category
Treatment - Drugs

2
Description
In control group, 0.1mg/kg Morphine will be infused
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Street address
golgasht street
City
Tabriz

Sponsors / Funding sources

1
Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali meshkini

Street address

Deputy of research, Faculty of Medicine, Golgasht street

City

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**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Samad shams Vahdati

Position

Assistant professor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****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