

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

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Name of organization / entity

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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

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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*