Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of propofol with subcutaneous Sumatriptane in treatment of acute migraine headache

Protocol summary

Summary

In order to compare the effect of Propofol with Sumatriptane on acute migraine headache. In a randomized double blinded clinical trial 90 patients aged between 18 and 45 years old who are admitted in emergency department because of acute migraine headache are enrolled in this study. Patients are allocated randomly in the two groups. Exclusion criteria are pregnancy; coronary or peripheral vascular disease; opium addiction and patients taken Ergotamine derivatives in the last 24 hours and patients don,t respond to treatment after one repetition of therapy . After evaluating patients headache by VAS.In Propofol group 2cc of normal saline is injected subcutaneous, 30 to 40 mg Propofol is injected as blouse titrated to sedation score 3 (sleep but arousable with sound) and then 1 to 2cc 1% Propofol injected every 3 to 5 minutes up to maximum 120 mg in20 to 30minuts.In Sumatriptane group 6 mg Sumatriptane is injected sub-cutaneous and then 3cc of normal saline is infused. Then patients re-evaluate by VAS criteria for headache and associated symptoms such as nausea vomiting and side effects of drugs, in 0.5, 1 and 2 hours after therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008174583N1**
Registration date: **2012-08-19, 1391/05/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-19, 1391/05/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of propofol with subcutaneous Sumatriptane in treatment of acute migraine headache

Public title

Comparison the effect of propofol with subcutaneous Sumatriptane in treatment of acute migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients aged between 18 and 45 years old with acute migraine headache admitted in emergency department or pain clinic. exclusion criteria are pregnancy; opium addiction; diastolic pressure

greater than 105. Sign and symptoms of organic headache peripheral and coronary artery disease.

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
Shahid Sadoughi University of Medical Sciences Yazd Iran

Street address
Yazd medical sciences university Bahonar squar Yazd Iran

City
Yazd

Postal code

Approval date
2012-02-27, 1390/12/08

Ethics committee reference number
P/17/1/153935

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43.0,G43.

ICD-10 code description
Migraine without aura [common mMigrain)migrane with aura [classical migraine]igraine],

Primary outcomes

1

Description
Headache severity

Timepoint
Before intervention; half an hour; one hour; and 2 hours after intervention

Method of measurement
Visual Analog Scale(VAS)

Secondary outcomes

1

Description
Accompanying symptoms including nausea vomiting photophobia and phonophobia

Timepoint
Before, half an hour, and one hour after intervention

Method of measurement
Observation

2

Description
Drug side effects including hypotension; bradycardia; nausea; vertigo; paresthesia

Timepoint
After intervention

Method of measurement
Observation

Intervention groups

1

Description
In intervention group after starting an IV line 2 cc of normal saline is injected sub-subcutaneously and then 3 cc of Propofol is prescribed as bolus and then 1 to 2 cc of 1% is administered every 3 to 5 minutes up to maximum 120 mg.

Category
Treatment - Drugs

2

Description
In control group after starting an IV line 6 mg of Somatriptane is injected subcutaneously and then 3cc of normal saline is injected as bolus and then 1to 2 cc every 3 to 5 minutes maximally up to 12 cc in 20 to 30 minutes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Seyed Hossein Moshtaghion
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Shahid Sadoughi Hospital, Safaieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences-Yazd, Iran
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
Shahid Sadoughi University of Medical Sciences-Yazd, Iran
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
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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