

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 in 20 to 30 minutes. In Sumatriptane group 6 mg Sumatriptane is injected subcutaneous 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

Name

Hossein Moshtaghion

Name of organization / entity

Yazd University of Medical Sciences

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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

Street address

Shahid Sadoughi Hospital, Safaieh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd,
Iran

Full name of responsible person

Dr fatemah ezaddini

Street address

Bahonar square, Shahid Sadoughi University of
Medical Sciences-Yazd, Iran

City

Yazd

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

Shahid Sadoughi University of Medical Sciences-Yazd,
Iran

Full name of responsible person

Dr Seyed Hossein Moshtaghion

Position

Assistant Professor of anesthesiology

Other areas of specialty/work

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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