

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effectiveness of intravenous Dexamethasone versus Propofol for pain relief in the Migraine headache in the Emergency Department in Imam Reza Hospital, Tabriz University of Medical Science.

#### Protocol summary

##### Summary

A prospective double blind randomized clinical trial was performed in Imam Reza teaching hospital in Tabriz-Iran. Ninety patients presenting to ED with Migraine headache were enrolled in two equal groups (I,II). In group I, we used intravenous propofol (10-20 mg every 3 -5 minutes) slowly and in group II, we used dexamethasone (approximately 0.15 mg/kg) slowly. Our inclusion criteria were as follows: A. At least five attacks fulfilling the criteria in B, C, D, and E. B. Attack lasts 4 to 72 hours with or without treatment. C. Headache has at least two of the following characteristics: 1. Unilateral location 2. Pulsating quality 3. Moderate to severe intensity 4. Aggravated by walking up stairs or similar routine physical activity D. During headache, at least one of the following: 1. Nausea or vomiting (or both) 2. Photophobia and phonophobia E. History, physical. and neurologic examination and, if appropriate, diagnostic tests to exclude related organic disease. Our exclusion criteria were as follows: 1-Patients who received narcotic, triptans or other vasoconstrictors like intravenous dihydroergotamine 2- Allergy to eggs or soya Pain explained by patients, based on VAS (Visual Analogue Scale) was recorded at the time of entrance to Emergency medicine Department, and in 5, 10, 20,30 and 45 minutes after injection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008122496N4**

Registration date: **2010-10-15, 1389/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-10-15, 1389/07/23

##### Registrant information

###### Name

Hassan Soleimanpour

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1329 1286

###### Email address

soleimanpourh@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Research Vice chancellor of Tabriz University of Medical Sciences

##### Expected recruitment start date

2009-07-23, 1388/05/01

##### Expected recruitment end date

2010-07-23, 1389/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of intravenous Dexamethasone versus Propofol for pain relief in the Migraine headache in the Emergency Department in Imam Reza Hospital, Tabriz University of Medical Science.

##### Public title

Effectiveness of intravenous Dexamethasone versus

Propofol for pain relief in Migraine headache in the Emergency Department in Imam Reza Hospital, Tabriz University of Medical Science.

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: A. At least five attacks fulfilling the criteria in B, C, D, and E. B. Attack lasts 4 to 72 hours with or without treatment. C. Headache has at least two of the following characteristics: 1. Unilateral location 2. Pulsating quality 3. Moderate to severe intensity 4. Aggravated by walking up stairs or similar routine physical activity D. During headache, at least one of the following: 1. Nausea or vomiting (or both) 2. Photophobia and phonophobia E. History, physical. and neurologic examination and, if appropriate, diagnostic tests to exclude related organic disease. Exclusion criteria: 1- Patients who received narcotic, triptans or other vasoconstrictors like intravenous dihydroergotamine 2- Allergy to eggs or soya

## **Age**

No age limit

## **Gender**

Both

## **Phase**

1-2

## **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**

Research Vice chancellor of Tabriz University of Medical Sciences

##### **Street address**

Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN

##### **City**

Tabriz

##### **Postal code**

51664

## **Approval date**

2009-06-04, 1388/03/14

## **Ethics committee reference number**

888

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Migraine headache

#### **ICD-10 code**

G43.0

#### **ICD-10 code description**

common migraine

## **Primary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

at 5, 10,20,30 and 45th minutes following intervention

#### **Method of measurement**

Visual Analogue Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intravenous Propofol 10-20 mg every 3 -5 minutes

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intravenous Dexamethasone approximately 0.15 mg/kg slowly

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam reza hospital

##### **Full name of responsible person**

Dr.Hassan Soleimanpour

##### **Street address**

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

##### **City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Vice chancellor of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mir Ali Eteraf Oskouei

**Street address**

Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

**City**

Tabriz

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Vice chancellor of 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.Hassan Soleimanpour

**Position**

Anesthesiologist/Assistant professor of Anesthesiology, MD

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

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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Hassan Soleimanpour

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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*