

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### **Analysis and Comparison of the Variations of Blood Flow velocity in Doppler Ultrasound of Brain Vessels before and after the Intra arterial Injection of Papaverine during the Operation of Patients Suffering from Brain Aneurysm in Al-Zahra Hospital, Isfahan, Iran during 2011-2012**

#### **Protocol summary**

##### **Summary**

Analysis and Comparison of the Variations of Blood Flow velocity in Doppler Ultrasound of Brain Vessels before and after the Intra arterial Injection of Papaverine during the Operation of Patients Suffering from Brain Aneurysm that decrease Blood Flow velocity cause to prevention & treat the vasospasm. The entrance criteria to the study included the followings: infliction to cerebral Aneurysm suffering from Sub Arachnoidhemorrhage and were candidates of surgical operation for any reason regardless of the time of hemorrhage; not being inflicted to Parkinson's disease; not being in complete heart block A.V condition; not being inflicted to Glaucoma; not being pregnant and the patient's consent. The patients that encountered brain death after the hemorrhage under Arachnoid were disregarded from the study. The procedure was as follows: the qualified patients were examined under the Microvascular Doppler Ultrasound (MDS) during the operation and before the Papaverine injection; and the blood flow velocity in cerebral arteries of these patients were measured, then 200mg Papaverine, by Insulin Syringe through the main arterials of brain proximal to Aneurysm, is injected intra arterially. Thirty minutes after the injection of medicine, the patients were examined by Doppler Ultrasound (MDS) again and of the arterial blood flowvelocity was measured.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2013010411996N1**

Registration date: **2013-01-26, 1391/11/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2013-01-26, 1391/11/07

##### **Registrant information**

###### **Name**

Mohamad Motahari

###### **Name of organization / entity**

Isfahan University of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 31 1673 4669

###### **Email address**

m\_motahari@resident.mui.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Isfahan University of Medical Sciences

##### **Expected recruitment start date**

2011-04-09, 1390/01/20

##### **Expected recruitment end date**

2012-08-21, 1391/05/31

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

Analysis and Comparison of the Variations of Blood Flow velocity in Doppler Ultrasound of Brain Vessels before and after the Intra arterial Injection of Papaverine during the Operation of Patients Suffering from Brain Aneurysm in Al-Zahra Hospital, Isfahan, Iran during 2011-2012

## Public title

Analysis Injection of Papaverine in the Brain Vessels for to prevent some complication of Brain bleeding

## Purpose

Prevention

## Inclusion/Exclusion criteria

The entrance criteria to the study included the followings: inflection to cerebral Aneurysm suffering from Sub Arachnoidhemorrhage and were candidates of surgical operation for any reason regardless of the time of hemorrhage; not being inflected to Parkinson's disease; not being in complete heart block A.V condition; not being inflected to Glaucoma; not being pregnant and the patient`s consent. The patients that encountered brain death after the hemorrhage under Arachnoid were disregarded from the study.

## Age

No age limit

## Gender

Both

## Phase

1

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

medical university of Isfahan

#### Street address

st.hezarjerib, medical university of Isfahan

#### City

Isfahan

#### Postal code

### Approval date

2011-02-20, 1389/12/01

### Ethics committee reference number

389467

## Health conditions studied

1

### Description of health condition studied

Vasospasm of cerebral vessels

### ICD-10 code

G45.9

### ICD-10 code description

Vasospasm of cerebral vessels

## Primary outcomes

1

### Description

Decrease Blood Flow velocity

### Timepoint

30 min

### Method of measurement

Doppler Ultrasound sec/cm

## Secondary outcomes

1

### Description

Increase Blood Flow velocity

### Timepoint

30 min

### Method of measurement

Doppler Ultrasound

## Intervention groups

1

### Description

The procedure was as follows: the qualified patients were examined under the Microvascular Doppler Ultrasound (MDS) during the operation and before the Papaverine injection; and the blood flow velocity in cerebral arteries of these patients were measured, then 200mg Papaverine, by Insulin Syringe through the main arterials of brain proximal to Aneurysm, is injected intra arterially. Thirty minutes after the injection of medicine, the patients were examined by Doppler Ultrasound (MDS) again and of the arterial blood flowvelocity was measured. Information of the patients were recorded in a checklist that included personal and case features of the patient, age, sex and the blood flowvelocity, before and after Papaverine injection. At the end, the data were analyzed by SPSS software version 20 using chi-square, two independent sample T test and paired sample T test.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Al-Zahra Hospital of Isfahan

**Full name of responsible person**

mohamad motahari

**Street address**

Dep. neurosurgery oh the Al-Zahra Hospital of Isfahan

**City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Medical Univercity of Isfahan

**Full name of responsible person**

Ms Toghiani

**Street address**

st.Hezar jerib ,Medical Univercity of isfahan

**City**

Isfahan

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

Yes

**Title of funding source**

Medical Univercity of Isfahan

**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**

Medical Univesity of Isfahan

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**Web page address****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*