

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Milrinone treatment vasospasm in patients with subarachnoid hemorrhage

Protocol summary

Study aim

Effect of Milrinone treatment on vasospasm in patients with subarachnoid hemorrhage

Design

This is a Clinical and double-blind clinical trial. 32 candidates for subarachnoid hemorrhage referred to Valiasr Hospital are entered. We will divide patients in two groups randomly.

Settings and conduct

This is a Clinical and double-blind clinical trial. 32 candidates for aneurysms referred to Valiasr Hospital are entered. The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind). An analyzer used to treat a patient don't aware.

Participants/Inclusion and exclusion criteria

Inclusion criteria: both of gender, Patients with subarachnoid hemorrhage and vasospasm
Exclusion criteria: Dissatisfaction

Intervention groups

During digital subtraction angiography, we inject 50 micrograms per kilogram melirinone initially and in following 0.5 to 0.75 micrograms per kilogram per minute melirinone for patients. We compare patients before and after angiography. During digital subtraction angiography, we inject routine drug for patients. It is repeat 10 minutes after angiography injection. We perform by a neurologist TransCranial Doppler sonography in control group.

Main outcome variables

Determine vasoaspm of the cerebrovascular

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N82**

Registration date: **2018-07-11, 1397/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-11, 1397/04/20**

Update count: **0**

Registration date

2018-07-11, 1397/04/20

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-29, 1396/08/07

Expected recruitment end date

2019-10-29, 1398/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Milrinone treatment vasospasm in patients with subarachnoid hemorrhage

Public title

Effect of Milrinone treatment vasospasm in patients with subarachnoid hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
both of gender Patients with subarachnoid hemorrhage and vasospasm
Exclusion criteria:
Dissatisfaction

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. Outcome evaluator and analyzer and participant are blind (double-blind). Outcome evaluator and analyzer don't aware from grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University Of Medical Sciences

Street address
Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Approval date
2017-05-01, 1396/02/11

Ethics committee reference number
IR.ARAK.MU.REC.1396.2

Health conditions studied

1

Description of health condition studied
subarachnoid hemorrhage

ICD-10 code
I60

ICD-10 code description
Nontraumatic subarachnoid hemorrhage

Primary outcomes

1

Description
vasospasm

Timepoint
Before and after intervention

Method of measurement
TransCranial Doppler sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: During digital subtraction angiography, we inject 50 micrograms per kilogram melirinone is initially and in following 0.5 to 0.75 micrograms per kilogram per minute melirinone for patients . It is repeat 10 minutes after angiography injection. We perform by a neurologist TransCranial Doppler sonography.

Category
Treatment - Drugs

2

Description
Control group: During digital subtraction angiography, we inject routine drug for patients . It is repeat 10 minutes after angiography injection. We perform by a neurologist TransCranial Doppler sonography.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital

Full name of responsible person
Dr Mohsen Dalvandi

Street address
Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person

Dr Alireza kamali
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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resident of neurosurgery
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Mohsen Dalvandi

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments