

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effects of Filgrastimin on Complications of patients with cerebral hemorrhage due to head trauma

Protocol summary

Summary

Aim of this study is the effects of Filgrastimin on Complications of patients with cerebral hemorrhage due to head trauma. This study is clinical trial and double blind. 68 patients will be entered to the emergency room in Valiasr hospital in Arak with brain hemorrhage resulting from head trauma. We will check hemoglobin and hematocrit and Platelets and Electrolytes before and in and after treatment. We will inject 150 microgram Filgrastimin subcutaneous in 4 day in intervention group (34 patients). We will inject normal saline in control group (34 patients). We follow up patients for embolism and deep vein thrombosis and paralyzed limb strength before and after treatment. We will record mortality and number of hospitalization days after treatment. Inclusion criteria: 18 years and more; patients with cerebral hemorrhage due to head trauma; level of consciousness between 9 -13 Exclusion criteria: alcohol consumption and addiction; allergy for drug; history of hypertension and diabetes and embolism and deep vein thrombosis; patient died 72 hours after admission

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020120258N30**

Registration date: **2017-02-14, 1395/11/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-06-14, 1395/03/25

Expected recruitment end date

2017-06-15, 1396/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Filgrastimin on Complications of patients with cerebral hemorrhage due to head trauma

Public title

The effects of Filgrastimin on Complications of patients with cerebral hemorrhage due to head trauma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 18 years and more; patients with cerebral hemorrhage due to head trauma; level of consciousness between 9 -13 Exclusion criteria: alcohol consumption and addiction; allergy for drug; history of hypertension and diabetes and embolism and deep vein thrombosis; patient died 72 hours after admission

Age

No age limit
Gender
Both
Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: 68
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2016-06-13, 1395/03/24

Ethics committee reference number

IR.ARAKMU.REC.1395.100

Health conditions studied

1

Description of health condition studied

cerebral hemorrhage due to head trauma

ICD-10 code

I61.1

ICD-10 code description

Intracerebral haemorrhage in hemisphere, cortical

Primary outcomes

1

Description

Blood pressure
Timepoint
Before and in and after treatment
Method of measurement
Barometer

2

Description

Hemoglobin

Timepoint

Before and in and after treatment

Method of measurement

Blood test

3

Description

Electrolytes

Timepoint

Before and in and after treatment

Method of measurement

Blood test

4

Description

Hematocrit

Timepoint

Before and in and after treatment

Method of measurement

Blood test

5

Description

Paralyzed limb strength

Timepoint

before and after treatment

Method of measurement

Physical examination

6

Description

deep vein thrombosis

Timepoint

before and after treatment

Method of measurement

CT venography

7

Description

number of hospitalization days

Timepoint

After treatment

Method of measurement

Observation

8

Description

Mortality

Timepoint

After treatment

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: We will inject 150 micro gram Filgrastimin subcutaneous in 4 day in intervention group (34 patients).

Category

Treatment - Drugs

2**Description**

Control group: We will inject normal saline in control group (34 patients).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Dr Arash Yazdanbakhsh

Street address

Valiasr Hospital, Arak

City

Arak

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

Vice chancellor for research, Arak University of Medical Sciences

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

Vice chancellor for research, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Morteza Gharibi

Position

Faculty, Emergency Medicine Specialist

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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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