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 squre, 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
Dr Mohammad Rafiee
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
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
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Valiasr Hospital, Valiasr square, Shahid Shirodi street
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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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Full name of responsible person

Dr Vaghef Farshin

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Assistant of Emergency Medicine

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