

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Filgrastim on Prognosis of Patients with acute Ischemic Stroke

#### Protocol summary

##### Study aim

The Effects of Filgrastim on Prognosis of Patients with acute Ischemic Stroke

##### Design

Aim of this study is evaluation Filgrastim on Prognosis of Patients with acute Ischemic Stroke. This study is clinical trial and double blind. 84 patients enter referring to emergency department of Valiasr Hospital in Arak with stroke symptoms.

##### Settings and conduct

This study is clinical trial and double blind. 84 patients enter referring to emergency department of Valiasr Hospital in Arak with stroke symptoms.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years and more; Patients with acute ischemic stroke Exclusion criteria: Drinking alcohol and addict; Incidence of side effects or the sensitivity of the drug; history of blood pressure, diabetes, embolism and DVT; death of the patient 72 hours after entering the emergency room

##### Intervention groups

We treat patients (42 person) by 150 milligram in 24 hours Filgrastim in 3 days in intervention group. We treat patients (42 person) 150 milligram in 24 hours normal saline in control group.

##### Main outcome variables

Effects of Filgrastim on prognosis clinical (power paralysis, condition of consciousness, motor status) of patients with acute Ischemic Stroke

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N63**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

##### Registration date

2018-01-22, 1396/11/02

##### 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

2016-06-19, 1395/03/30

##### Expected recruitment end date

2018-06-20, 1397/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of Filgrastim on Prognosis of Patients with acute Ischemic Stroke

##### Public title

The Effects of Filgrastim on Prognosis of Patients with acute Ischemic Stroke

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

18 years and more Patients with acute ischemic stroke

**Exclusion criteria:**

Drinking alcohol and addict Incidence of side effects or the sensitivity of the drug History of blood pressure, diabetes, embolism and DVT Death of the patient 72 hours after entering the emergency room

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization with random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee 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**

2016-06-13, 1395/03/24

**Ethics committee reference number**

IR.ARAK.MU.REC.1395.101

**Health conditions studied****1****Description of health condition studied**

acute Ischemic Stroke

**ICD-10 code**

I63.9

**ICD-10 code description**

Cerebral infarction, unspecified

**Primary outcomes****1****Description**

Hemoglobin

**Timepoint**

Before and during treatment and 4 weeks after treatment

**Method of measurement**

blood test

**2****Description**

power of the paraplegic organ

**Timepoint**

Before and during treatment and 4 weeks after treatment

**Method of measurement**

Physical examination

**3****Description**

Awareness status

**Timepoint**

Before and during treatment and 4 weeks after treatment

**Method of measurement**

Glasgow Coma Scale

**4****Description**

Motion status

**Timepoint**

Before and during treatment and 4 weeks after treatment

**Method of measurement**

Physical examination

**5****Description**

Hematocrit

**Timepoint**

Before and during treatment and 4 weeks after treatment

**Method of measurement**

blood test

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: We treat patients(42 person) by 150 milligram in 24 hours Filgrastim in 3 days in intervention group.

### Category

Treatment - Drugs

2

### Description

Control group: We treat patients(42 person) 150 milligram in 24 hours normal salin in control group.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Valiasr hospital

#### Full name of responsible person

Dr Morteza Gharibi

#### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

#### City

Arak

#### Province

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#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

+98 86 3222 2003

#### Email

mgharibi@arakmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr Aliarash Anoshirvani

#### Street address

Vice chancellor for research, Payambar azam complex, Basij squire, Sardasht, Arak

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#### Province

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#### Postal code

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#### Phone

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#### Fax

+98 86 3222 2003

#### Email

anoshirvani@arakmu.ac.ir

#### 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 Morteza Gharibi

#### Position

Assistant professor, emergency Medicine Specialist

#### Latest degree

Specialist

#### Other areas of specialty/work

Emergency Medicine

#### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

#### City

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#### Province

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#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

+98 86 3222 2003

#### Email

gharibi@arakmu.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Ebrahimimonfared

**Position**

Assistant professor, Neurologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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**Email**

mirhosseini@gmail.com

**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 Ebrahimi Monfared

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

They have to write letters to the professors and the university.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Leila Mirhosseini Ardakani

**Position**

resident of Emergency Medicine Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Province**