

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the effect of GCSF injection in treatment of COVID-19 patients with lymphopenia (less than 1000)

#### Protocol summary

##### Study aim

Evaluation of the effect of GCSF injection in treatment of COVID-19 patients with lymphopenia (less than 1000) in Kosar Hospital

##### Design

Clinical trial with control group, Randomized, Single-center, Sample size 10 people.

##### Settings and conduct

Kowsar Hospital in Semnan. Granulocyte colony-stimulating factor (GCSF) stimulant dose is administered to patients as an intravenous dose. Then a blood test is done one day and 3 days after the injection to check the number of lymphocytes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Covid 19; Conscious consent of the patient. Exclusion criteria: Without lymphopenia.

##### Intervention groups

Intervention group: Granulocyte colony-stimulating factor (GCSF) stimulant dose is administered to patients as an intravenous dose. Then a blood test is done one day and 3 days after the injection to check the number of lymphocytes. Control group: Patients are treated according to national protocol. Only for comparison with intervention group.

##### Main outcome variables

Blood lymphocytes.

#### General information

##### Reason for update

##### Acronym

Granulocyte - colony stimulating factor (G-CSF)

##### IRCT registration information

IRCT registration number: **IRCT20200502047268N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

##### Registration date

2020-05-16, 1399/02/27

##### Registrant information

###### Name

IRAN Akram alizadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3344 1021

###### Email address

alizadeh.a@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of GCSF injection in treatment of COVID-19 patients with lymphopenia (less than 1000)

##### Public title

Evaluation of the effect of GCSF injection in treatment of COVID-19 patients with lymphopenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

COVID-19 pneumonia Conscious consent of the patient

**Exclusion criteria:**

Without lymphopenia

**Age**

No age limit

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 10

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

**Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3514799442

**Approval date**

2020-04-21, 1399/02/02

**Ethics committee reference number**

IR.SEMUMS.REC.1399. 13

**Health conditions studied**

1

**Description of health condition studied**

Covid-19

**ICD-10 code**

U07.01

**ICD-10 code description**

Coronavirus infection, unspecified

**Primary outcomes**

1

**Description**

Blood lymphocytes

**Timepoint**

Before entering the study and 3 days after drug injection

**Method of measurement**

Using hemocytometer

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Granulocyte colony-stimulating factor (GCSF) stimulant dose is administered to patients as an intravenous dose. Then a blood test is done one day and 3 days after the injection to check the number of lymphocytes.

**Category**

Treatment - Drugs

2

**Description**

Control group: Patients are treated according to national protocol. Only for comparison with intervention group.

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Kosar hospital

**Full name of responsible person**

Amir sarabi

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alizadehbio@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kokhaie

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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**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Amir Sarabi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Oncology

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Akram Alizadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Tissue Engineering

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## Person responsible for updating data

**Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

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**Position**

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Ph.D.

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available