

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

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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

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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