

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Efficacy of different methods of administration of combination regimen including dexamethasone, IV-IG and Interferone beta for treatment of patients with severe COVID-19: a randomized controlled trial

Protocol summary

Study aim

To determine the efficacy of different methods of administration of combination regimen including dexamethasone, IV-IG and Interferone beta for treatment of patients with severe COVID-19

Design

This is a phase 2 randomized controlled trial with 3 parallel arms without blinding. Participants will be recruited in 3 arms including control, intervention 1 and intervention 2 arms. Participants will be allocated in the study arms using a simple randomization method.

Settings and conduct

The study will be conducted in hospitals of Golestan province. Data on demographic and risk factors will be collected using a questionnaire. Clinical data as well as lab data (SpO₂,...) and imaging results will be collected from the hospital information system.

Participants/Inclusion and exclusion criteria

Inclusion: age 18-70 years old; severe COVID 19 disease.
Exclusion: need for intubation; contraindication of corticosteroids, IV IG and interferon beta; pregnancy or lactation.

Intervention groups

Control arm: receive standard treatment for COVID19 according to the protocol of MOH of Iran. Intervention 1: receive standard treatment for COVID19 and combination of dexamethadone, IV-IG and Interferon beta at admission. Intervention 2: receive standard treatment for COVID19 and combination of dexamethasone, IV-IG and Interferon beta 48 hours after admission.

Main outcome variables

Improvement in SpO₂ (increasing in level of SpO₂ to levels higher than 90%)

General information

Reason for update

Acronym

DIIC19

IRCT registration information

IRCT registration number: **IRCT20120225009124N4**

Registration date: **2020-04-02, 1399/01/14**

Registration timing: **prospective**

Last update: **2020-04-02, 1399/01/14**

Update count: **0**

Registration date

2020-04-02, 1399/01/14

Registrant information

Name

Gholamreza Roshandel

Name of organization / entity

Golestan University of Medical Sciences/ Golestan Research Center of Gastroenterology and Hepatology

Country

Iran (Islamic Republic of)

Phone

+98 17 3225 1910

Email address

roshandel@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of different methods of administration of combination regimen including dexamethasone, IV-IG and Interferone beta for treatment of patients with severe COVID-19: a randomized controlled trial

Public title
Efficacy of dexamethasone, IV-IG and Interferone beta for treatment of patients with severe COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-70 years Sever COVID19 disease with the following criteria: SpO2 below 90% and respiratory rate higher 24 per minute; Involvement of more than 50% of lung in CT-scan
Exclusion criteria:
Need for intubation at the time of admission
Contraindication of corticosteroids, IV IG and interferon beta
Pregnancy, lactation

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into study groups using a simple randomization method. The allocation process will be concealed to the physician and researchers. Allocation concealment will be made using sealed envelope system.

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 Golestan University of Medical Sciences

Street address

Sahst-kola, Falsafi campus

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-04-02, 1399/01/14

Ethics committee reference number

IR.GOUMS.REC.1399.004

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Improvement in SpO2 (increasing in level of SpO2 to levels higher than 90%)

Timepoint

After finishing the intervention

Method of measurement

By Pulse oximeter

Secondary outcomes

1

Description

Duration of stay in hospital

Timepoint

After finishing the intervention

Method of measurement

Reviewing patient hospital file

2

Description

Intubation

Timepoint

After finishing the intervention

Method of measurement

Reviewing patient hospital file

3

Description

Mortality

Timepoint

After finishing the intervention

Method of measurement

Reviewing patient hospital file

Intervention groups

1

Description

Control group: Receive standard treatment for COVID19 according to the protocol of MOH of Iran (antiviral drugs and hydroxychloroquine)

Category

Treatment - Drugs

2

Description

Intervention group 1: Receive standard treatment for COVID19 and combination of dexamethadone, IV-IG and Interferon beta at admission

Category

Treatment - Drugs

3

Description

Intervention group 2: Receive standard treatment for COVID19 and combination of dexamethasone, IV-IG and Interferon beta 48 hours after admission

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi hospital

Full name of responsible person

Dr Nafiseh Abdolahi

Street address

Sayyad Shirazi Boulevard

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4917867439

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+98 17 3225 1910

Email

grcgh@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammadreza Honarvar

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Nafiseh Abdolahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Gholamreza Roshandel

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Golestan Research Center of Gastroenterology and Hepatology, Sayyad Shirazi hospital

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Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Gholamreza Roshandel

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Title and more details about the data/document

Anonymized individual data

When the data will become available and for how long

After publication of the paper

To whom data/document is available

All interested researchers

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

Deputy of research of Golestan University of Medical Sciences

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

By submission an approved research proposal to deputy of research of Golestan University of Medical Sciences

Comments