Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Efficacy of different methods of administeration of combination regiemn 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 administeration of combination regiemn 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 contortionists, 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 administeration of combination regiemn 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: SPpO2 below 90% and respiratory rate higher 24 per minute; Involvement of more that 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 intervetion

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
City
Gorgan
Province
Golestan
Postal code
4917867439
Phone
+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
Street address
Sast-Kola, Falsafi campus
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1660
Email
info@goums.ac.ir
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
Street address
Sayyad Shirazi boulevard, Sayyad Shirazi hospital
City
Gorgan
Province
Golestan
Postal code
4917867439
Phone
+98 17 3225 1910
Email
n_abdolahi2002@yahoo.com

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

Street address
Golestan Research Center of Gastroenterology and Hepatology, Sayyad Shirazi hospital

City
Gorgan

Province
Golestan

Postal code
4917867439

Phone
+98 17 3225 1910

Fax

Email
roshandel@goums.ac.ir

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
Epidemiology

Street address
Golestan Research Center of Gastroenterology and Hepatology, Sayyad Shirazi hospital

City
Gorgan

Province
Golestan

Postal code
4917867439

Phone
+98 17 3225 1910

Fax

Email
roshandel@goums.ac.ir

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