

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Dec 2023

### **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 (SpO<sub>2</sub>,...) 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 SpO<sub>2</sub> (increasing in level of SpO<sub>2</sub> 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

##### 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

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**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.

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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**