

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Study of Dexamethasone effects on the improvement of clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

#### Protocol summary

##### Study aim

Evaluation of Dexamethasone effects on improvement of Iranian COVID-19 patients

##### Design

This study is a clinical trial with a control group, with single blind double-sided groups in the second phase. Which will be performed on 200 outpatients with COVID-19 disease. Patients are randomly divided into two groups of intervention and placebo based on the method of Permuted balanced block randomization and according to the patient file number.

##### Settings and conduct

A total of 200 outpatients with COVID-19 with respiratory symptoms referred to clinics in Imam Khomeini, Amir-Alam, Emam Ali and Ziaian hospitals are enrolled.

##### Participants/Inclusion and exclusion criteria

Patients with Covid 19 who test positive for SARS-CoV-2 by RT-PCR or diagnosed by CT scan criteria and saturated oxygen between 95-90% are randomly entered into the study. Exclusion criteria: Having a history of underlying diseases such as diabetes, malignancies, renal and heart failure, uncontrolled hypertension, other active infections, use of immunosuppressive drugs and corticosteroids, pregnant women or breastfeeding

##### Intervention groups

Control group: will receive standard regimen for COVID-19. Dexamethasone group: will receive standard regimen for COVID-19 plus 8 mg Dexamethasone (If the patient's condition does not change, the dose will repeat after 48 hours).

##### Main outcome variables

Clinical symptoms including: mortality rate, blood oxygen saturation level, need for oxygen therapy and laboratory tests before and one and two weeks after treatment will be evaluated and recorded in a questionnaire.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201015049030N1**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

##### Registration date

2020-11-07, 1399/08/17

##### Registrant information

##### Name

Mohammadreza Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2811

##### Email address

mr-salehi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-11, 1399/06/21

##### Expected recruitment end date

2020-12-10, 1399/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Study of Dexamethasone effects on the improvement of clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

## Public title

Effect of Dexamethasone on treatment of COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Outpatients with Covid 19 confirmed by positive PCR test for SARS-CoV-2 or confirmed by abnormal CT scan finding (bilateral, sub pleural, peripheral ground glass opacities), With blood oxygen saturation between 90-95% Patients with severe respiratory symptoms such as cough, shortness of breath and severe shortness of breath or CRP above 20 or after three days of standard treatment worsened symptoms of the disease, including exacerbated fevers, aggravated weakness or aggravated shortness of breath based on the physician's clinical judgment

### Exclusion criteria:

Patients with a history of underlying disease such as diabetes, malignancies, renal and heart failure, uncontrolled hypertension, and taking immunosuppressive drugs and corticosteroids Patients with other active infections Pregnant or lactating women

## Age

From **18 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Assignment of patients to the intervention and control groups will be done based on the Permuted balanced block randomization method and according to the patients' file numbers.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study patients don't know which group of them will use the medicine. Physician and clinicians team know about the medicine and intervention groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice-Chancellor in Research Affairs Tehran University of Medical Science

##### Street address

Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1416753955

#### Approval date

2020-09-10, 1399/06/20

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.432

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 disease

#### ICD-10 code

U07.2, U07

#### ICD-10 code description

COVID-19

## Primary outcomes

### 1

#### Description

O2 saturation

#### Timepoint

Before, one and two weeks after dexamethasone treatment

#### Method of measurement

Pulse Oximeter

### 2

#### Description

Mortality rate

#### Timepoint

Before and after dexamethasone treatment

#### Method of measurement

Observation

### 3

#### Description

Need for an oxygen therapy

#### Timepoint

Before and after dexamethasone treatment

#### Method of measurement

Clinical

## 4

### **Description**

Constitutional

### **Timepoint**

Before, one and two weeks after dexamethasone treatment

### **Method of measurement**

Clinical

## 5

### **Description**

Needs of hospitalization

### **Timepoint**

Before and after treatment

### **Method of measurement**

Observation

## **Secondary outcomes**

## 1

### **Description**

CRP laboratory test

### **Timepoint**

Before, one and two weeks after dexamethasone treatment

### **Method of measurement**

Para-clinical

## 2

### **Description**

CBC laboratory test

### **Timepoint**

Before, one and two weeks after dexamethasone treatment

### **Method of measurement**

Para-clinical

## **Intervention groups**

## 1

### **Description**

Intervention group: 100 outpatients with Covid 19 with respiratory symptoms who in addition to their standard treatment will receive 8mg Dexamethasone (If patient's condition does not change, the dose will repeat after 48 hours).

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: 100 outpatients with Covid 19 with respiratory symptoms who are received standard treatment

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Imam khomeini Hospital

#### **Full name of responsible person**

Mohamadreza Salehi

#### **Street address**

Imam Khomeini Hospital Complex, Tohid Squire

#### **City**

Tehran

#### **Province**

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#### **Postal code**

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#### **Phone**

+98 21 6658 1594

#### **Email**

salehi.mohamad3@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Ziaeian

#### **Full name of responsible person**

Saeed Reza Jamali Moghadm

#### **Street address**

Tehran Province, Tehran, Ghaleh Marghi St., Abuzar St., District 17 Municipality, No.

#### **City**

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## 3

### **Recruitment center**

#### **Name of recruitment center**

Amir-Alam Hospital

#### **Full name of responsible person**

Ali Asadolahi Amin

#### **Street address**

North Sadi Street, Enghelab Avenue

#### **City**

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asadollahia@sina.tums.ac.ir

## 4

### Recruitment center

**Name of recruitment center**

Emam Ali Hospital

**Full name of responsible person**

Mojtaba Hedayat Yaghoobi

**Street address**

Emam Ali Hospital, Azimieh, Karaj

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

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Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd

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vcr@tums.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohamadreza Salehi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahdi Mahmoudi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Akhtari

**Position**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

It will be published as an article

**When the data will become available and for how long**

After printing the article

**To whom data/document is available**

All medical professionals and scientists

**Under which criteria data/document could be used**

There is no restriction on access to information

**From where data/document is obtainable**

Dr. Mohamad Reza Salehi, Tehran University of Medical Science

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

Refer to the project supervisor

**Comments**