

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Tehran

Postal code

1419733141

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

Tehran

Province

Tehran

Postal code

3651113667

Phone

+98 21 5517 6813

Email

saeedjamali@yahoo.com

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

Tehran

Province

Tehran

Postal code

6511111457

Phone

+98 21 6670 6106

Email

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

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3256 2358

Email

hyaghooby@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

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

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8163 3685

Email

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

Street address

Imam Khomeini Hospital Complex, Tohid Squire

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6658 1594

Email

salehi.mohamad3@gmail.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8822 0067

Email

mahmoudim@tums.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8822 0067

Email

m.akhtari@ut.ac.ir

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