

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effectiveness and complication of dexamethasone at doses of 8 and 24 mg in the treatment of in Hospitalized Patients with Covid-19

Protocol summary

Study aim

Comparison of the effectiveness and complication of dexamethasone at doses of 8 and 24 mg in the treatment of in Hospitalized Patients with Covid-19

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 3 on 60 patients. A randomization table was used for randomization

Settings and conduct

This study is performed on patients with Covid 19 admitted to Al-Zahra Medical Center in Isfahan. After obtaining the consent of eligible patients, patients are divided into two groups using a randomization table, one group treated with dexamethasone at a dose of 8 mg daily for 10 days or until discharge and the other group treated with dexamethasone at a dose of 24 mg daily Up to 3 days and then 8mg daily for 7 days or until discharge. During treatment, fever, shortness of breath based on a modified Borg scale, the patient's O2sat level with and without oxygen therapy and tests such as quantitative CRP, LDH, ferritin, lymphocyte percentage, absolute neutrophil to lymphocyte ratio will be evaluated Drug side effects will be followed up.

Participants/Inclusion and exclusion criteria

Age over 18 years, evidence of SARS-CoV-2 virus by RT-PCR test, moderate to severe CTscan involvement, 80-93% O2sat level without oxygen therapy, at least 7 days after the onset of symptoms

Intervention groups

Injection of dexamethasone at a dose of 8 mg daily in the control group and injection of dexamethasone at a dose of 24 mg daily for up to 3 days in the intervention group and its change to 8 mg daily after 3 days

Main outcome variables

Efficacy and side effects of dexamethasone at doses of 8 and 24 mg

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190606043826N2**

Registration date: **2021-07-01, 1400/04/10**

Registration timing: **prospective**

Last update: **2021-07-01, 1400/04/10**

Update count: **0**

Registration date

2021-07-01, 1400/04/10

Registrant information

Name

Marzieh Mollaei Ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 0931

Email address

mollaei-m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness and complication of dexamethasone at doses of 8 and 24 mg in the treatment of in Hospitalized Patients with Covid-19

Public title

Comparison of the effectiveness and complication of dexamethasone at doses of 8 and 24 mg in the treatment of in Hospitalized Patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized Patients with Covid-19

Exclusion criteria:

Pregnancy Immunodeficiency diseases chronic liver and kidney diseases or gastrointestinal bleeding
Glucocorticoid use in the last 1 month

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants (they have no information about the type of drug injected) Responsible for data collection (on the data collection sheet, the name of the type of drug received by the patient is not mentioned) Data analyzer (in the data sent to the analyzer, the treatment groups are listed as A and B)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services, Hezar Jerib St

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.MUI.MED.REC.1400.160

Health conditions studied

1

Description of health condition studied

covid 19 pneumonia

ICD-10 code

u10

ICD-10 code description

Multisystem inflammatory syndrome associated with COVID-19

Primary outcomes

1

Description

Determination of mean arterial blood oxygen saturation with and without oxygen therapy

Timepoint

At the beginning of hospitalization and 3, 5, 7 and 10 days later

Method of measurement

pulse oxymeter

2

Description

Shortness of breath score based on modified Borg scale

Timepoint

At the beginning of hospitalization and 3, 5, 7 and 10 days later

Method of measurement

modified Borg scale

3

Description

Number of days required for mechanical ventilation

Timepoint

daily

Method of measurement

Counting days under mechanical ventilation

4

Description

Measurement of serum levels of C-reactive protein

Timepoint

At the beginning of hospitalization and 3, 5, 7 and 10 days later

Method of measurement

laboratory test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with covid 19 treated with dexamethasone 24 mg daily for 3 days and then 8 mg daily for 10 days or until discharge

Category

Treatment - Drugs

2**Description**

Control group: Patients with Covid 19 who are treated with dexamethasone 8 mg daily for 10 days or discharge time

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital, Isfahan

Full name of responsible person

Somayeh Sadeghi Haddad Zavareh

Street address

Al-Zahra Hospital , Sofa Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Street address

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

No

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Somayeh Sadeghi Haddad Zavareh

Position

Assistant 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

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Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

All data is potentially shareable after unidentifying individuals

When the data will become available and for how long

After analyzing the results, the data access period is free

To whom data/document is available

Academic Institutions and Researchers

Under which criteria data/document could be used

For use in future studies.

From where data/document is obtainable

Corresponding Author

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

Send an email to the author and get the information

Comments