

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Study the effect of Steroid on the outpatient treatment Covid-19 patients

Protocol summary

Study aim

Study the effect of corticosteroid on the outpatient treatment Covid-19 patients

Design

70 outpatient patients with covid-19 will be randomly assigned to intervention and control (placebo) groups. Randomization will be done by simple randomization via www.randomization.com. This is a phase 3 trial with parallel groups and triple blinded.

Settings and conduct

This study will be held in 3 outpatient center. Blinding will be triple blind, so that neither patient, physician, the outcome assessor and data analyzer are not aware of the groups. patients in intervention and placebo groups will be treated for 5 days and followed for 1 month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definite case of Covid-19, age over 18, presented in day 5th-10th from the start of sign and symptoms; Exclusion criteria: severe cases with SpO2 under 90, using an antiviral in previous two weeks, previous infection with covid-19, using an steroid in previous two weeks, being under treatment with steroid, previous allergic to Steroid, pregnancy, lactating, immunosuppressive state

Intervention groups

Intervention: Prednisolone 50 milligram, once daily for 5 days; Control: Placebo, 1 pill per day for 5 days

Main outcome variables

Treatment failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037964N2**

Registration date: **2020-12-02, 1399/09/12**

Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**

Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Babak Amra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

amra@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Steroid on the outpatient treatment Covid-19 patients

Public title

The effect of Steroid on the outpatient treatment of Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

definite case of Covid-19 age over 18 presented in day 5th-10th from the start of sign and symptoms

Exclusion criteria:

Severe cases with SpO2 under 90 Using an antiviral in previous two weeks Previous infection with covid-19 Using an steroid in previous two weeks Being under treatment with steroid Previous allergic to Steroid Pregnancy Lactating Immunosuppressive state

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using simple randomization. A random string will be made using www.randomization.com for 70 number in two groups. each patient will be assigned with a number by the physician. then this number will be matched by the random string by research assistant and the patient will be assigned to group A or B according to that.

Blinding (investigator's opinion)

Triple blinded

Blinding description

patients will be assigned to groups Intervention (prednisolone) or Control (placebo). placebo is designed just the same as Prednisolone and in a same pack. packages is defined by A or B and neither of patient, physician, researchers, outcome assessor and data analyzer do not know the meaning of codes. Just the research assistant is aware of codes.

Placebo

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

Hezarjerib st.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.MUI.MED.REC.1399.781

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**

Treatment failure

Timepoint

days 3, 7, 14, 21, 28 from the start of treatment

Method of measurement

interview with patients

Secondary outcomes

empty

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

Intervention group: patients in this group will be treated by Prednisolone 50 milligram, once daily for 5 days

Category

Treatment - Drugs

2**Description**

Control group: patients in this group receive placebo, 1 pill daily for 5 days

Category

Placebo

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

Dr. Amra clinic

Full name of responsible person

Dr. Babak Amra

Street address

Sepahsalar St.

City

Isfahan

Province

Isfahan

Postal code

8166863543

Phone

+98 31 3776 6293

Email

amrababak@gmail.com

2**Recruitment center****Name of recruitment center**

Dr. soltaninejad clinic

Full name of responsible person

Dr. Forough Soltaninejad

Street address

No. 409, Noor building, Shamsabadi St.

City

Isfahan

Province

Isfahan

Postal code

8134654669

Phone

+98 31 3234 0059

Email

f.soltaninejad@med.mui.ac.ir

3**Recruitment center****Name of recruitment center**

Dr. Salahi clinic

Full name of responsible person

Dr. Mehrdad Salahi

Street address

First floor, Iranian Clinic, Ferdosi St.

City

Shahinshahr

Province

Isfahan

Postal code

8314896713

Phone

+98 31 4527 0780

Email

salahimehrdad@yahoo.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezarjerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3060

Email

research@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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

Babak Amra

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Respiratory disease

Street address

Isfahan University of Medical Sciences, Hezarjerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Fax**Email**

Amra@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Babak Amra

Position

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after being unidentified

When the data will become available and for how long

one month after the publication of results

To whom data/document is available

All researches are allowed to apply for the data

Under which criteria data/document could be used

For using in systematic review analysis

From where data/document is obtainable

email to amrababak@gmail.com

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

The application email will be sent to the chancellor for research of Isfahan University of Medical Sciences, after the approval the data will be sent to the applicant

Comments