Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Šteroid, pregnancy, lactating, immunosupressive 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)
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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 Immunosupressive 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
Isfehan

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.
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2

Recruitment center
Name of recruitment center
Dr. soltaninejad clinic
Full name of responsible person
Dr. Forough Soltaninejad
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No. 409, Noor building, Shamsabadi St.
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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.
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Isfehan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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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
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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
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