Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of doxycycline in the treatment of outpatients with Covid-19 .

Protocol summary

Study aim
Evaluation of the effectiveness of doxycycline in the treatment of outpatients with Covid-19 referred to Shahid Beheshti Hospital in Hamadan in 2020-2021

Design
This is a non blind randomized clinical trial, in which 88 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
This study is performed in Shahid Beheshti Hospital in Hamadan.In addition to standard treatment, 44 outpatients with suspected Qovid 19 outpatient treatment receive Doxycycline is taken orally for 10 days. 44 outpatients with suspected Qovid 19 control groups receive only standard treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Minimum age 18 and maximum age 80 years,Do not take doxycycline for the last five days, Patients with definitive diagnosis of Covid 19 (RT-PCR) candidate for outpatient treatment with pulmonary involvement score on CT scan equal to or below 8,Patients suspected of Covid-19 based on clinical signs and manifestations of CT scan and laboratory results candidate for outpatient treatment. Exclusion criteria: Hospitalization, patients with no indications for outpatient treatment based on national protocol, pregnancy, patients with a history of allergic reaction or doxycycline sensitivity, underlying disease.

Intervention groups
44 patients with Covid receive doxycycline capsules at a dose of 100 mg twice daily for 10 days with standard care and medication and in the control group 44 patients receive standard care and medication.

Main outcome variables
Improvement of clinical symptoms, hospitalization, mortality rate and side effects of doxycycline

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N16**
Registration date: **2021-08-25, 1400/06/03**
Registration timing: **prospective**

Last update: **2021-08-25, 1400/06/03**
Update count: **0**

Registration date
2021-08-25, 1400/06/03

Registrant information

Name
Mohammad Faryadras

Name of organization / entity
Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 3428 9706

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-02, 1400/07/10

Expected recruitment end date
2022-03-16, 1400/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of doxycycline in the treatment of outpatients with Covid-19 .

Public title
Evaluation of the effectiveness of doxycycline in the treatment of outpatients with Covid-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum age 18 and maximum age 80 years Do not take doxycycline for the last five days Patients with definitive diagnosis of Covid 19 (RT-PCR) candidate for outpatient treatment with pulmonary involvement score on CT scan equal to or below 8 Patients suspected of Covid-19 based on clinical signs and manifestations of CT scan and laboratory results candidate for outpatient treatment.

Exclusion criteria:
Hospitalization Patients with no indications for outpatient treatment based on national protocol. pregnancy Patients with a history of allergic reaction or Doxycycline. Underlying disease

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2021-07-10, 1400/04/19

Ethics committee reference number
IR.UMSHA.REC.1400.305

Health conditions studied

1

Description of health condition studied
COVID-19, virus identified

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Improvement of clinical symptoms

Timepoint
Start of study and 3, 7, 14 days after study

Method of measurement
Questionnaire - telephone follow-up and

2

Description
hospitalizations

Timepoint
7 and 14 days after study

Method of measurement
Telephone follow up

3

Description
Mortality rate

Timepoint
7 and 14 days after study

Method of measurement
Telephone follow up

Secondary outcomes

1

Description
Side effects of doxycycline
Timepoint
7 and 14 days after study
Method of measurement
Telephone follow up

Intervention groups

1

Description
Intervention group: Doxycycline capsules are given orally made by Iran Daru Company (Iran) 100 mg twice a day for 10 days along with standard care and medication measures for Covid patients.
Category
Treatment - Drugs

2

Description
Control group: Standard care and medication measures for Covid patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Zohreh Kahramfar
Street address
Hamedan University of Medical Science, Shahid Fahmideh Street, Hamedan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Hamid Sadeghibidar
Position
Resident of Internal Medicine
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is not a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available