

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 Covid 19 outpatient treatment receive Doxycycline is taken orally for 10 days. 44 outpatients with suspected Covid 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)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

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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6517838678

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kahramfar@umsha.ac.ir

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

Medical Physics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zohreh Kahramfar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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