

# 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

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838678

#### Phone

+98 81 3825 2440

#### Email

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

### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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### Phone

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### Email

info.research@umsha.ac.ir

### 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

#### Street address

Shahid Beheshti Hospital, Eram Ave.

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#### Postal code

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#### Phone

+98 81 3838 0283

#### Email

hamid.sadeghibidar@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zohreh Kahramfar

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hamedan University of Medical Science, Shahid Fahmideh Street,

**City**

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**Postal code**

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**Phone**

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**Email**

kahramfar@umsha.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zohreh Kahramfar

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hamedan University of Medical Science, Shahid Fahmideh Street, Hamedan

**City**

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**Province**

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**Postal code**

6517838678

**Phone**

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**Email**

kahramfar@umsha.ac.ir

## 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