Clinical trial of minocycline against COVID-19

Protocol summary

Study aim
Evaluation the effect of minocycline in covid-19 patients

Design
A randomized, blinded, placebo controlled clinical trial with a parallel group design of 40 patients, randomizing with the table of random numbers.

Settings and conduct
This study will be performed on outpatients. In this study, 40 patients with covid-19 disease were selected and randomly assigned to two groups of 20 individuals. Patients in the standard diet control group will receive standard coronavirus treatment with placebo. In addition to the standard diet, patients in the treatment group will be treated with 100 mg of minocycline BID for at least 2 weeks. Patients are monitored at intervals of 3 days, 1 week and 2 weeks after receiving the drug or placebo in terms of time interval until clinical and laboratory symptoms improve.

Participants/Inclusion and exclusion criteria
People over 18 years of age with a diagnosis of coronavirus based on clinical and laboratory symptoms; home quarantine and outpatients

Intervention groups
The control group receives standard anti-coronavirus drugs with placebo. In addition to the common anticorona virus drugs, the treatment group also receives minocycline.

Main outcome variables
Time interval until lymphopenia improves Time interval until CRP normalizes Time interval until clinical symptoms improve (fever, cough and myalgia)

General information

Reason for update
Correction of minocycline spell

Acronym
IRCT registration information
IRCT registration number: IRCT20081019001369N4
Registration date: 2020-04-11, 1399/01/23

Registration timing: prospective
Last update: 2020-04-13, 1399/01/25
Update count: 1
Registration date
2020-04-11, 1399/01/23

Registrant information
Name
Hossein Hosseinazadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3180 1193
Email address
hosseinazadehh@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-20, 1399/02/01
Expected recruitment end date
2020-07-22, 1399/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of minocycline against COVID-19

Public title
Effect of minocycline on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with covid-19 symptoms Indication of home
quarantine and outpatient medication; Age range 18 to 65

**Exclusion criteria:**
Patients connected to a catheter
Patients under chemotherapy
Patients taking cytotoxic drugs or corticosteroids
Pregnant and lactating patients
Patients with severe renal insufficiency
Patients with liver failure
Diabetic patients

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**
- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization in three stages: 1- Random sequence generation: this step simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The drug and placebo are given as a same-color and -size capsules in boxes labeled with the letters A and B in box. The medical staff, the patient and the data collector are not aware of the nature of the drug or placebo, and only the executor of research project is aware of the nature of the contents of the two capsules.

**Placebo**
Used

**Assignment**
Parallel

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee
Medical Ethics Committee of Mashhad University of Medical Sciences

**Street address**
Blv.Vakilabad 2- School of Pharmacy-1365-91775

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948954

**Approval date**
2020-04-06, 1399/01/18

**Ethics committee reference number**
IR.MUMS.REC.1399.053

**Health conditions studied**

1

**Description of health condition studied**
Covid-19

**ICD-10 code**
U07.1

**ICD-10 code description**
COVID-19 Disease

**Primary outcomes**

1

**Description**
Time interval until clinical symptoms improve

**Timepoint**
3 days, 1 week and 2 weeks after treatment

**Method of measurement**
time of recovery

**Secondary outcomes**

1

**Description**
Fever

**Timepoint**
3 days, 1 week and 2 weeks after treatment

**Method of measurement**
Thermometer

2

**Description**
Lymphopenia
Timepoint
3 days, 1 week and 2 weeks after treatment

Method of measurement
Cell counter device

3
Description
CRP
Timepoint
3 days, 1 week and 2 weeks after treatment
Method of measurement
CRP kit

Intervention groups

1
Description
Intervention group: In addition to the standard treatment regimen for COVID-19, the minocycline capsule 100 mg will be given two times a day for 2 weeks.
Category
Treatment - Drugs

2
Description
Control group: Patients on the standard treatment regimen for COVID-19 will receive placebo capsules two times a day for 2 weeks. The placebo is formulated in capsules of the same shape and size as the drug capsules and contains avicel and aerosil.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Hasheminejad Hospital
Full name of responsible person
Javad Dehghan Nayyeri
Street address
Mofateh Boulevard, Vahid Street
City
 Mashhad
Province
Razavi Khorasan
Postal code
۶١۳۳۱۹۷۳۱۹
Phone
+98 51 3273 7011
Email
DehghanMj@mums.ac.ir

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Hosseinzadeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Blv. Vakilabad2-School of Pharmacy, 1365-91775
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1193
Fax
+98 51 1882 3251
Person responsible for scientific inquiries

Contact
- Name of organization / entity: Mashhad University of Medical Sciences
- Full name of responsible person: Hossein Hosseinzadeh
- Position: Professor
- Latest degree: Ph.D.
- Other areas of specialty/work: Medical Pharmacy
- Street address: Blv. Vakilabad2-School of Pharmacy, 1365-91775
- City: Mashhad
- Province: Razavi Khorasan
- Postal code: 9177948954
- Phone: +98 51 3180 1193
- Fax: +98 51 1882 3251
- Email: hosseinzadehh@mums.ac.ir

Sharing plan
- Deidentified Individual Participant Data Set (IPD): Undecided - It is not yet known if there will be a plan to make this available
- Study Protocol: Undecided - It is not yet known if there will be a plan to make this available
- Statistical Analysis Plan: Undecided - It is not yet known if there will be a plan to make this available
- Informed Consent Form: Undecided - It is not yet known if there will be a plan to make this available
- Clinical Study Report: Undecided - It is not yet known if there will be a plan to make this available
- Analytic Code: Undecided - It is not yet known if there will be a plan to make this available
- Data Dictionary: Not applicable

Person responsible for updating data

Contact
- Name of organization / entity: Mashhad University of Medical Sciences
- Full name of responsible person: Hossein Hosseinzadeh
- Position: Professor
- Latest degree: Ph.D.
- Other areas of specialty/work: Pharmacology
- Street address: Blv. Vakilabad2-School of Pharmacy, 1365-91775
- City: Mashhad
- Province: Razavi Khorasan
- Postal code: 9177948954
- Phone: +98 51 3180 1193
- Fax: +98 51 1882 3251
- Email: hosseinzadehh@mums.ac.ir