

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy of standard and Arbidol treatments in COVID-19 outpatients

Protocol summary

Study aim

This study will be performed to determine the efficacy of Arbidol and the standard treatment regimen according to national guidelines and compare their effectiveness in treating outpatients with COVID-19.

Design

A phase II, two-arm, parallel, randomized, double-blind, controlled clinical trial on 100 COVID-19 outpatients. For randomization, random blocks will be used.

Settings and conduct

This study will be performed on outpatients with COVID-19 in an outpatient clinic under infectious disease specialists' supervision. After confirmation of the disease with the rt-PCR test and, if the patients meet the inclusion criteria, they will be randomly assigned to one of the two groups. Also, the participants and some of the researchers will be blinded.

Participants/Inclusion and exclusion criteria

Patients with the new coronavirus infection 2019 (COVID-19) confirmed by the rt-PCR test with the approval of an infectious disease specialist and an indication for outpatient treatment will randomly be allocated into two groups: intervention group (Arbidol plus standard treatment) and control group (standard treatment).

Intervention groups

The control group will be given standard treatment, including famotidine, cetirizine, N-acetylcysteine, bromhexine, naproxen, and fluticasone propionate inhaler, and the intervention group will also receive the standard regimen plus two capsules of arbidol (manufactured by Pharmstandard, Russia) with the dose of 40 mg q8hours. Treatment in both groups will continue for 7 days.

Main outcome variables

Cessation of fever; Improve ESR, CRP, and CBC test results; Negative rt-PCR test; Improve oxygen saturation; No need for mechanical ventilation; Improve pulmonary involvement on CT scan

General information

Reason for update

To change the patient recruitment date, phase of the study, and sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049134N1**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **prospective**

Last update: **2021-01-17, 1399/10/28**

Update count: **1**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Mohammad Barary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 0124

Email address

m.barary@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of standard and Arbidol treatments in COVID-19 outpatients

Public title

Efficacy of Arbidol in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People over the age of 65 who are in high-risk groups (with a history of high blood pressure, diabetes, BMI > 30, COPD, cancer, and etc.) Confirmation of the diagnosis of COVID-19 by chest CT scan and/or rt-PCR Signing an informed consent form

Exclusion criteria:

History of allergies to these drugs Use arbidol before hospitalization Pregnant women Respiratory failure and need for mechanical ventilation Renal and/or hepatic failure Anemia and thrombocytopenia Coagulopathy Autoimmune or immune deficiency disorders

Age

From **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Unit randomization is done by block method with a block size of 4. For each of the 6 possible cases for the quadruple block, the numbers are assigned as follows AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6) With the help of a table of random numbers, the numbers between 1 and 6 are selected and the treatment allocation list is determined according to each number. To execute the generated random sequence, the method of hiding coded boxes or cans is used. In this method, the cans are numbered in a random sequence and inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written, is provided to the executor with the condition that the boxes are completely sealed and The researcher assigns patients to the standard intervention and treatment group based on the order of patients' admission. Tools: Create random sequences of 4 random blocks Concealment to execute random sequences on study participants will be done. How to make blocks: Randomly select the block and read the letters from right to left. Hiding will be done by the method of cans that are numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and some researchers who act as clinicians, and statisticians will be blinded. Names of the researchers for whom blinding will be performed: 1) Mostafa Javanian 2) Masoumeh Bayani 3) Mahmoud Sadeghi-Haddad-Zavareh 4) Mehran Shokri

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Department of infectious disease, Rouhani Hospital, Ganj afrooz blvd., Babol

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.MUBABOL.REC.1399.283

Health conditions studied**1****Description of health condition studied**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Time of the removal of the symptoms

Timepoint

Up to 1 month after the end of the study

Method of measurement

Examination of the patients by infectious disease specialists in an outpatient clinic

2

Description

hospitalization required

Timepoint

Up to 1 month after the end of the study

Method of measurement

Examination of the patients by infectious disease specialists in an outpatient clinic

3

Description

Life-threatening conditions

Timepoint

Up to 1 month after the end of the study

Method of measurement

Examination of the patients by infectious disease specialists in an outpatient clinic

4

Description

Death

Timepoint

Up to 1 month after the end of the study

Method of measurement

Examination of the patients by infectious disease specialists in an outpatient clinic

Secondary outcomes

empty

Intervention groups

1

Description

Control group: standard approved treatment regimen for COVID-19, including famotidine, cetirizine, N-acetylcysteine, bromhexine, naproxen, and fluticasone inhaler for 7 days

Category

Treatment - Drugs

2

Description

Intervention group: standard approved treatment regimen for COVID-19, including famotidine, cetirizine, N-acetylcysteine, bromhexine, naproxen, and fluticasone inhaler plus arbidol (manufactured by Pharmstandard, Russia) at the dose of two 40 mg capsules every 8 hours for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani hospital outpatient clinic

Full name of responsible person

Mostafa Javanian

Street address

Ganj afrooz blvd., Ayatollah Rouahni hospital

City

Babol

Province

Mazandaran

Postal code

4714743568

Phone

+98 11 3223 8301

Email

mjavanian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Vice-chancellor for research and technology affairs, Babol University of Medical Sciences, University sq.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 7667

Fax

+98 11 3219 7667

Email

rezaghadimi@yahoo.com

Web page address

<http://research.mubabol.ac.ir/about/?id=350>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mohammad Barary

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.88, Khosravan 10 ave., Moallem 12 st., Shariaty blvd.

City

Babol

Province

Mazandaran

Postal code

4714743568

Phone

+98 11 3236 0124

Email

m1377b@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mostafa Javanian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Vice-Chancellor for public health affairs, Shahid Modarres blvd.

City

Babol

Province

Mazandaran

Postal code

4714934937

Phone

+98 11 3233 6875

Fax

+98 11 3236 3875

Email

mjavanian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mohammad Barary

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.88, Khosravan 10 ave., Moallem 12 st., Shariaty blvd.

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Email

m1377b@gmail.com

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All participants' personal data can be shared after unidentifying individuals.

When the data will become available and for how long

Six months after the end of the study and publication of the article

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no specific preconditions.

From where data/document is obtainable

They should send their request to the person in charge of the study, Dr. Mostafa Javanian, with the e-mail address: mjavanian@gmail.com

What processes are involved for a request to access data/document

On average, it will take two weeks to process the application.

Comments