Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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)

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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 infectiuos 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
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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.
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Fax
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Email
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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

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Person responsible for updating data

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Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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