

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the Effectiveness of Tenofovir antiviral drug beside routine drug regime (standard of care) in COVID-19 patients

Protocol summary

Study aim

Comparison of the Effectiveness of Tenofovir antiviral drug beside routine drug regime (standard of care) in COVID-19 patients

Design

Clinical trial with control group, parallel group trial, open label, phase 2 on 60 patients. Replacement randomization was used.

Settings and conduct

In both study groups (control and case), on the first day, patients will receive routine drug regime (standard of care). In addition to the above drugs Alfamed Tenofovir, Case is given daily at 25 mg daily for 7 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People over 18 years of age. 2. Positive Real-time PCR test for SARS-CoV-2 virus positive after sampling (nasopharyngeal and oropharyngeal swab samples). 3. Pneumonic manifestations of the virus. In CT scans of the lungs, they should be clearly visible, with a 4% lower O2 Saturation of 93% exclusion criteria: 1- History of renal failure, 2- Taking drugs that interfere with Tenofovir and 3- Patients who have been included in other clinical trial studies

Intervention groups

Case group: Get the Tenofovir + standard of care Control group: Get the standard of care

Main outcome variables

Reduce the length of admission time, Reduce the length of ICU admission time, preventing the progression of the disease to acute respiratory distress syndrome (ARDS), Reducing fever, increasing oxygen saturation, Reducing dyspnea, Reducing Respiratory rate, Decreased heart rate.

General information

Reason for update

The standard of care regimens approved by the Ministry of Health differed from the time of the trial at the time of

registration. Also, the study method was changed from a double blinding study to an open-label study.

Acronym

Ahvaz TAF study

IRCT registration information

IRCT registration number: **IRCT20200422047168N1**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**

Update count: **1**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Zahra Shokati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 5678

Email address

zahrashokati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Tenofovir antiviral drug beside routine drug regime (standard of care) in COVID-19 patients

Public title

Clinical trial study on the therapeutic effect of Tenofovir besides routine drug regime (standard of care) in patients with Coronavirus disease 2019 (COVID-19)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- People over 18 years of age, 2- Real-time PCR positive test result for SARS-CoV-2 virus was positive after sampling (nasopharynx and oropharynx swab samples). 3. The manifestations of pneumonia caused by the virus in CT scans of their lungs are quite obvious. 4- They have 93% or lower O2 Saturation percentage

Exclusion criteria:

1- History of renal failure, 2- Taking drugs that interfere with Tenofovir 3. Patients who have been admitted to other clinical trials

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the Restricted randomization method of block randomization. Blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

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

Ethics committee of Jundishapur University of Medical Sciences

Street address

Alimentary Tract Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6163837194

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.AJUMS.REC.1399.082

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19, confirmed cases, positive test result

Primary outcomes

1

Description

Reduce the mortality rate of patients with Covid-19

Timepoint

days 0-7

Method of measurement

Based on the percentage of discharged Covid-19 patients

Secondary outcomes

1

Description

Treatment period

Timepoint

0-7

Method of measurement

Based on the days numbers of the drug usage

2

Description

Duration of infection

Timepoint

0-7

Method of measurement

Based on the patient's clinical symptoms

3

Description

Duration of admission time

Timepoint

0-7

Method of measurement

Number of admission days due to Covid-19

4

Description

Duration of ICU admission time

Timepoint

0-7

Method of measurement

Number of ICU admission days due to Covid-19

5

Description

Fever

Timepoint

0-7

Method of measurement

Rising body temperature

6

Description

Blood oxygen saturation percentage

Timepoint

0-7

Method of measurement

O2 saturation percentage

7

Description

Respiratory rate

Timepoint

0-7

Method of measurement

respiratory rate per minute

8

Description

heart rate

Timepoint

0-7

Method of measurement

heart rate per minute

9

Description

Discharge situation

Timepoint

0-7

Method of measurement

Alive or dead

10

Description

Use non-invasive respiratory methods

Timepoint

0-7

Method of measurement

Patients percentage that be supported by non-invasive breathing methods

11

Description

Use invasive respiratory methods

Timepoint

0-7

Method of measurement

Patients percentage that be supported by invasive breathing methods

Intervention groups

1

Description

Intervention group: On the first day, patients will receive routine drug regime (standard of care) daily for 7 days. In addition to the above drugs, Alfamed Tenofovir is given to 25 mg daily for 7 days.

Category

Treatment - Drugs

2

Description

Control group: On the first day, patients will receive routine drug regime (standard of care) for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Razi hospital

Full name of responsible person

Ali akbar Shayesteh

Street addressKhuzestan - Ahvaz - Imam Khomeini Hospital -
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zahrashokati@gmail.com

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Shokati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Shokati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available