Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 lable, 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
Khouzestan

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
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Khuzestan - Ahvaz - Imam Khomeini Hospital - Alimentary Research Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Shokati
Position
Assistant professor
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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