Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the efficacy and side effects of combination therapy of Kaletra and Hydroxychloroquine in comparison with Atazanavir / Ritonavir and Hydroxychloroquine in the treatment of patients with COVID-19

Protocol summary

Study aim
Comparison of effectiveness and side effects of combination therapies in the treatment of patients with COVID-19 infection in Arak city in 2020

Design
Clinical trials with a control group in the form of parallel, double-blind, non-randomized trials was performed on 108 patients with COVID-19.

Settings and conduct
The study is performed at Corona Patients ward of Ayatollah Khansari Hospital in Arak and the method of blindness is that the type of treatment is based on the opinion of the treating physician and the evaluator and the patient are unaware of the type of treatment and therefore the study will be double blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are hospitalized in the ward and are considered to have a moderate case of COVID-19 (need to be admitted to the ward and not ICU hospital); satisfy with entering the study. Non-inclusion criteria: Severe form of the disease that requires Ribavirin; Hospitalization in the ICU and the need for intubation; Mild form of the disease that does not require hospitalization

Intervention groups
Control group: 200 mg Hydroxychloroquine on the first day and 2 tablets of Kaletra every 12 hours from the second day onwards for at least 5-7 days. Intervention group: 200 mg Hydroxychloroquine every 12 hours and Atazanavir / ritonavir daily for at least 5-7 days.

Main outcome variables
The Oxygen saturation in the patient's blood during hospitalization and treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200517047485N1**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **prospective**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**

Registration date
2020-05-29, 1399/03/09

Registrant information

Name
hossein mazaherpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3232 3473

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-20, 1399/03/31

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and side effects of combination

therapy of Kaletra and Hydroxychloroquine in comparison with Atazanavir / Ritonavir and Hydroxychloroquine in the treatment of patients with COVID-19

Public title
Comparison of combination therapies of COVID_19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are hospitalized in the ward and are considered to have a moderate form of COVID-19 (need to be admitted to the ward and not ICU hospital) Patients who are satisfied with the study entry
Exclusion criteria:
The patient has a severe disease that requires Ribavirin The patient need to be hospitalized in the ICU or intubation The patient has a mild form of the disease that does not require hospitalization (patients with a history of outpatient treatment for COVID-19). Patients with specific underlying disease and / or need to take specific medications
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in the study and researcher and evaluator of the consequences are unaware of the type of treatment, given that the type of medication is determined by the treating physician.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Vali-e-Asr Hospital; Vali-e-Asr Square
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2020-04-06, 1399/01/18
Ethics committee reference number
IR.ARAKMU.REC.1399.006

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Oxygen saturation following combination therapy for COVID-19
Timepoint
Daily examination of the patient during hospitalization
Method of measurement
pulse oxymetry

Secondary outcomes

1

Description
Treatment outcome (recovery rate)
Timepoint
At the end of treatment and hospitalization
Method of measurement
physical examination and patient file

2

Description
mortality rate
Timepoint
At the end of treatment and hospitalization
Method of measurement
patient file

3

Description
complications of disease

Timepoint
At the end of treatment and hospitalization
Method of measurement
physical examination and patient file

Intervention groups

1

Description
Intervention group: Hydroxychloroquine 200 mg tablet, every 12 hours with Atazanavir / Ritonavir tablets daily for at least 5-7 days
Category
Treatment - Drugs

2

Description
Control group: Hydroxychloroquine 200 mg tablet, every 12 hours for the first day with 2 tablets of Kaletra every 12 hours for at least 5-7 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari hospital, Arak University of Medical Sciences
Full name of responsible person
Hossein Mazaherpour
Street address
Ayatollah Khansari Hospital, at the end of Daneshgah street
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3814957558
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Arak University of Medical Sciences Complex; Basij square
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3848176341
Phone
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alikamaliir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Hossein Mazaherpour
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data can be shared after making people unidentifiable
When the data will become available and for how long
Start the access period 6 months after the publication of the results
To whom data/document is available
Researchers working in academic centers
Under which criteria data/document could be used
Other conditions are not acceptable
From where data/document is obtainable
executor of research
What processes are involved for a request to access data/document
Send email to project executor
Comments