

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Mar 2023

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 mazahepour

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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Email

h.mazaherpour@arakmu.ac.ir

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Arak University of Medical Sciences Complex; Basij square

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

Arak University of Medical Sciences

Full name of responsible person

Hossein Mazaherpour

Position

Associate professor

Latest degree

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Other areas of specialty/work

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