

# 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

h.mazahepour@arakmu.ac.ir

##### 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

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3367 5000

**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

**Street address**

Arak University of Medical Sciences Complex; Basij square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Phone**

+98 86 3417 3645

**Email**

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

**Street address**

Valiasr Hospital; Valiasr square

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086-32222003-8

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

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**Full name of responsible person**

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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**

Specialist

**Other areas of specialty/work**

Infectious diseases

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