Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

Assessment of the effect of Tranilast on the efficacy of antiviral drug regimens in the treatment of patients with severe COVID19

Protocol summary

Study aim

Evaluation of the effect of Tranilast on the effectiveness of antiviral drug treatment in patients with severe COVID19

Design

This study is a two arm parallel group clinical trial that will be done in Ahvaz hospital. Randomization is done through block method. Sample size of this study is 60 patients that divided equally into two groups)intervention and control group . intervention and control group treat with the same method, except the case group that receiveTranilast tablet. This a phase 3 clinical trial. In both groups clinical outcome and side effects are evaluated.

Settings and conduct

A randomized clinical trial that will be done in Ahvaz hospital. According to inclusion and exclusion criteria, patients are randomly divided into 2 grups. Both groups receive the same treatment. Intervention group will receive Tranilast tablet daily until 14 days.Blinding is not done in our study.

Participants/Inclusion and exclusion criteria

.Age ≥18 years Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19 Lung involvement confirmed with chest imaging Hospitalized with: Fever (axillar or oral temperature ≥ 38.0 °centigrade(C) or ≥38.6°centigrade tympanic or rectal) or Respiratory rate >24/min Or Cough Less than 8 days since illness onset Willingness of study participant to accept randomization to any assigned treatment arm Acceptance of non-participation in another study before the 28th day of the study

Intervention groups

Both intervention and control group receive routine treatment for two weeks. Intervention group receive 2 Tranilast tablet 100 mg for 14 days.

Main outcome variables

Time to clinical recovery,respiratory signs، Intubation rate,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200419047128N1**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **prospective**

Last update: **2020-04-22, 1399/02/03**
Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Ali Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3331 1061

Email address

akhodadadi2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-04, 1399/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Tranilast on the efficacy of antiviral drug regimens in the treatment of patients with severe COVID19

Public title
Tranilast in COVID19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥18 years Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19 Lung involvement confirmed with chest imaging Hospitalized with: Fever (axillar or oral temperature ≥ 38.0 °centigrade(C) or ≥38.6°centigrade tympanic or rectal) or Respiratory rate >24/min Or Cough Less than 8 days since illness onset Willingness of study participant to accept randomization to any assigned treatment arm Acceptance of non-participation in another study before the 28th day of the study
Exclusion criteria:
Autoimmune diseases (lupus, MS, etc.) Hepatic failure Hepatit B, C, pregnant and lactating women Not consent to participate in the study
Age
From **16 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two Therapeutic groups by random method and used 6 blocks method. Individuals are the randomization unit , making a random sequence is by using statistical software(WinPepi11.0). Allocation concealment is by assigning unique codes
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 Ahvaz University of medical sciences
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2020-04-11, 1399/01/23
Ethics committee reference number
IR.AJUMS.REC.1399.050

Health conditions studied

1

Description of health condition studied
COVID19
ICD-10 code
U07.1
ICD-10 code description
U07.1

Primary outcomes

1

Description
efficacy of Tranilast in severe Covid19 pneumonia
Timepoint
Daily until discharge and then weekly until 14 days
Method of measurement
history, Laboratory tests, CT scan of the chest,

Secondary outcomes

1

Description
Blood oxygen saturation percentage
Timepoint
Before and ten days after starting treatment
Method of measurement
Pulse oximeter

2

Description
Cough rate
Timepoint
Before and ten days after starting treatment
Method of measurement
Physical examination

3

Description
C-Reactive Protein (CRP)
Timepoint
Before and fourteen days after starting treatment

Method of measurement
ELISA (enzyme-linked immunosorbent assay)

4

Description
IL1
Timepoint
Before and 14 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

5

Description
IL6
Timepoint
Before and 14 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

6

Description
CBC
Timepoint
Before and 14 days after starting treatment
Method of measurement
Cell Counter

Intervention groups

1

Description
Intervention group: 2 Tabs Tranilast (TAIYO) from Takeda Pharmaceutical, daily until 14 days. Both case and control group will be received routine drugs.
Category
Treatment - Drugs

2

Description
Control group: this group doesnt receive extra drugs. Both groups receive routine drugs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Ali Khodadadi
Street address
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6155819953
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohamad Badavi
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6135539345
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Badavi-m@ajums.ac.ir
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
Ali khodadadi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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