Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Assessment of the effect of Tranilast (novel NLRP3 Inflammasome inhibitor) 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 receive300 mg daily for 7 days (100 mg PO TDS). 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 300 mg daily for 7 days (100 mg PO TDS).Participants in this study, as well as outcome assessors, were kept blind

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: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 3 Tranilast tablet 100 mg for 7 days.

Main outcome variables

Time to clinical recovery,respiratory signs، Intubation rate,Number of ICU-admitted patients، Duration of ICU-admission، neutrophil-lymphocyte ratio (NLR), erythrocyte sedimentation rate (ESR) ، C-reactive protein (CRP).

General information

Reason for update

In order to record the clinical trial information more accurately, some changes in the study design, inclusion and exclusion criteria have been updated. The ICD-10 code description was revised.

Acronym

IRCT registration information

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

Last update: **2021-07-04, 1400/04/13**
Update count: **1**

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

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Tranilast (novel NLRP3 Inflammasome inhibitor) 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 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 arterial blood O2 saturation under 93% non-pregnant females

Exclusion criteria:

Autoimmune diseases (lupus, MS, etc.) Hepatic failure Hepatit B, C, pregnant and lactating women use of antioxidants, anti-inflammatory and immunosuppressant drugs kidney failure known allergy to Tranilast

Age

From **18 years** old to **85 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

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

COVID-19, virus identified

Primary outcomes

1

Description

ICU-admitted patients

Timepoint

after treatment

Method of measurement

Record information in a checklist by a trained nurse

2

Description

Duration of ICU-admission

Timepoint

after treatment

Method of measurement

Record information in a checklist by a trained nurse

3

Description

deaths

Timepoint

After the intervention until the 28th day

Method of measurement
Record information in a checklist by a trained nurse

4

Description
neutrophil-lymphocyte ratio (NLR)
Timepoint
End of day 7
Method of measurement
White blood cell count

5

Description
C-reactive protein
Timepoint
End of day 7
Method of measurement
ELISA

Secondary outcomes

1

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

2

Description
IL1
Timepoint
Before and 7 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

3

Description
IL6
Timepoint
Before and 7 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

4

Description
CBC
Timepoint
Before and 7 days after starting treatment
Method of measurement
Cell Counter

5

Description
TNF
Timepoint
Before and 7 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

6

Description
D-dimer
Timepoint
Before and 7 days after starting treatment
Method of measurement
ELISA (enzyme-linked immunosorbent assay)

7

Description
SGPT
Timepoint
Baseline and days 7
Method of measurement
blood biochimecal test

8

Description
SGOT
Timepoint
Baseline and days 7
Method of measurement
blood biochimecal test

Intervention groups

1

Description
Intervention group: 3 Tabs Tranilast (TAIYO) from Takeda Pharmaceutical, daily until 7 days. Both intervention and control groups 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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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
Phone
+98 61 3311 3815
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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
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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