# 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**
Amanieh
**City**
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**Postal code**
6155819953
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akhodadadi2@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mohamad Badavi
**Street address**
Amanieh
**City**
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**Province**
Khouzestan
**Postal code**
6135539345
**Phone**
+98 61 3311 3815
**Email**
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