

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2020

Evaluation of Tissue Plasminogen Activator (tPA) in comparison of anticoagulation for treatment of critical COVID 19 patient

Protocol summary

Study aim

Evaluation of thrombolytic and anticoagulant in treatment of COVID-19 patients

Design

This study is a randomized control trial with three arm parallel group without double blind. We have three group, thrombolytic, UFH, and control. Randomization performed with Randlist software

Settings and conduct

This is a RCT of Tabriz, university of medical sciences. The patients will be divided to three group. Two cases and control group. First will be started on tPA 25 mg over 2 hours and 22 mg next 22 hours. Second group on therapeutic dose of anticoagulation (UFH with traumatic dose) and third group will be control with usual medications.

Participants/Inclusion and exclusion criteria

Critical COVID patients with d.Dimer more than 3000 ng/ml

Intervention groups

The patients will started on thrombolytic (tPA) or UFH and third group will be as a control .

Main outcome variables

Some main outcome of this study are improve of oxygenation, SOFA score and decrease of mortality

General information

Reason for update

Acronym

TACOVID

IRCT registration information

IRCT registration number: **IRCT20200515047456N1**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Farid Rashidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4901

Email address

fr2652@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-17, 1399/03/28

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Tissue Plasminogen Activator (tPA) in comparison of anticoagulation for treatment of critical COVID 19 patient

Public title

The role of anticoagulant and thrombolytic in treatment of COVID patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

COVID patients with P/F ratio less than 100 D.dimer more

than 3000 without response to other medications

Exclusion criteria:

Active bleeding Platelet less than 30000 Without any contraindication for thrombolytic therapy

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by block method and Randlist software according to Seed schedule with 420059136 number

Blinding (investigator's opinion)

Single blinded

Blinding description

Only participants in this study were blinded, given that the patients are unconscious and under mechanical ventilation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Farid Rashidi, MD, Tuberculosis and Lung diseases research center, Imam Reza Hospital, Daneshgah St, Tabriz

City

Tabriz

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East Azarbaijan

Postal code

5166614756

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.TBZMED.REC.1399.127

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

Improve of oxygenation

Timepoint

From first to 6th days of study

Method of measurement

Arterial blood gas

2

Description

Improve SOFA score

Timepoint

From first to 6th days of study

Method of measurement

Questionnaire

3

Description

Improve compliance

Timepoint

From first to 6th days of study

Method of measurement

Ventilator parameter

4

Description

decrease d.Dimer level

Timepoint

From first to 6th days of study

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Without placebo

Category

Treatment - Drugs

2

Description

Intervention group: first intervention group, anticoagulant. , the patients will be started on unfractional heparin. Blood sample will tale to keep PTT more than 50

Category

Treatment - Drugs

3

Description

Intervention group: second intervention group, thrombolytic (tPA). The will be started 25 mg over 2 hours and 25 mg for next 22 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hostital

Full name of responsible person

Farid Rashidi, MD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Dr. Mohammad Samiea

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

10

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

Tabriz University of Medical Sciences

Full name of responsible person

Farid Rashidi

Position

Assistance professor of medicine

Latest degree

Subspecialist

Other areas of specialty/work

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

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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

Demographic information

When the data will become available and for how long

Six month after publication

To whom data/document is available

Researchers who work in university

Under which criteria data/document could be used

Only for information

From where data/document is obtainable

Via e.mail

What processes are involved for a request to access data/document

Send a request via e.mail

Comments