Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of pentoxifylline in reducing the complications of Covid _19

Protocol summary

Study aim
Evaluation of the effect of pentoxifylline in reducing the complications of Covid _19

Design
Randomized, non-blind, clinical trail with parallel intervention and control group, with 100 Covid 19 patients.

Settings and conduct
This study was done on 100 Covid_ 19 patients in Sina hospital of Tabriz University of Medical Sciences. Patients will receive pantoxifylline 400 mg tablet thrice daily with meal.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: PCR Positive from nasopharyngeal specimen for covid 19 or evidence indicating Covid 19 disease,Moderate to mild symptoms,Less than 7 days after the onset of symptoms Ability to swallow,Age between 18 and 75 and Exclusion criteria are:Shock or failure of several organs, Chronic liver disease,Chronic kidney disease,Pregnancy and lactation,Participation in other clinical studies and Concomitant use of drugs that interact severely with pentoxifylline.

Intervention groups
This randomized, non blind clinical study will be performed on 100 selected patients according to the inclusion and exclusion criteria. Intervention group will receive 400 mg pentoxifylline tablets 3 times a day for 1 month with the standard diet of the Ministry of Health. The condition of patients will be evaluated daily with laboratory and clinical parameters and finally recorded in predesignated checklists. The control group will receive only the standard regimen of the Ministry of Health for 1 month.

Main outcome variables
Ṣerum Lactate Dehydrogenase (LDH) level , Serum C_reactive protein (CRP)level ,Percentage of Oxygen saturation in arterial blood(SPO2), prothrombin time (PT) and Partial Thromboplastin Time (PTT) ,Serum Procalcitonin level ,Serum Ferritin and D_dimer level and Serum level Brain natriuretic peptide (NT_ProBNP).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170609034406N8**
Registration date: **2021-08-26, 1400/06/04**
Registration timing: **prospective**

Last update: **2021-08-26, 1400/06/04**
Update count: **0**

Registration date
2021-08-26, 1400/06/04

Registrant information

Name
Afshin Gharekhani

Name of organization / entity
Faculty of Pharmacy/Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 3334 1315

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pentoxifylline in reducing the complications of Covid _19

Public title

Investigation of the effect of pentoxifylline on Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive PCR test for nasopharyngeal sample or certain evidence indicating Covid-19 disease Moderate to mild symptoms onset of symptoms within 7 days Ability to swallow Age between 18 and 75

Exclusion criteria:

Shock state or multi-organ failure Chronic liver disease Chronic kidney disease Pregnancy and lactation Participation in other clinical studies Receiving drugs with severe interaction with pentoxifylline

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Permuted Block Randomization method will be used for entering patients into control and treatment groups. There will exist 25 blocks with equal number of patients from each group in this study. Random numbers will be generated by using the Microsoft Excel Spreadsheet Software to randomize blocks and patients allocation.

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 Tabriz University of Medical Sciences

Street address

Research Vice-Chancellor, Third floor, No 2 central building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5766414766

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.TBZMED.REC.1399.1045

Health conditions studied

1

Description of health condition studied

COVID _19

ICD-10 code

U10.9

ICD-10 code description

Multisystem inflammatory syndrome associated with COVID_19

Primary outcomes

1

Description

Serum Procalcitonin level

Timepoint

At the beginning and end of the study

Method of measurement

Procalcitonin kit

2

Description

Serum Ferritin level

Timepoint

At the beginning and end of the study

Method of measurement

Ferritin kit

3

Description

Serum NT_ProBNP level (Brain natriuretic peptide)

Timepoint

At the beginning and end of the study

Method of measurement

Nt_ProBNP ELISA Kit

4

Description

Serum D_dimer level

Timepoint
At the beginning and end of the study.
Method of measurement
D_dimer ELISA kit

5

Description
Serum LDH (Lactate Dehydrogenase) level
Timepoint
At the beginning and end of the study
Method of measurement
DGKC Kit

6

Description
Partial Thromboplastin Time (PTT) and prothrombin Time (PT)
Timepoint
At the beginning and end of the study
Method of measurement
PTT and PT Kit

7

Description
Saturation of Peripheral Oxygen in arterial blood (SPO2)
Timepoint
At the beginning and end of the study.
Method of measurement
Arterial Blood Gas (ABG Test)

8

Description
Serum C_ reactive protein (CRP) level
Timepoint
At the beginning and end of the study
Method of measurement
CRP ELISA Kit

Secondary outcomes

1

Description
Reducing the length of hospital stay of patients
Timepoint
At the end of study
Method of measurement
Comparing the number of hospitalization days between the intervention group and control group

2

Description
Improving the quality of lung lesions
Timepoint
At the beginning and end of the study.
Method of measurement
CT_Scan of lungs

3

Description
Change in the sense of smell
Timepoint
At the beginning and end of the study.
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group (Pentoxifylline recipient + standard care): 100 patients with COVID-19 diagnosis will be included in the study according to the inclusion and exclusion criteria and will receive 400mg pentoxifylline tablet (produced by Amin pharmaceutical company in Iran) three times daily for 1 month along with the standard care of the Ministry of Health protocol.
Category
Treatment - Drugs

2

Description
Control group: In this clinical study, the control group will receive only the standard care of the Ministry of Health protocol for COVID-19 patients for 1 month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital of Tabriz University of Medical Sciences
Full name of responsible person
Dr Afshin Gharekhani
Street address
No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz
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5166614766
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Fax
Email
gharekhania@tbzmed.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Afshin Gharekhani

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No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz

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Grant name

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
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
Tabriz University of Medical Sciences

Full name of responsible person
Dr Afshin Gharekani

Position
University faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz

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Email
gharekhania@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Afshin Gharekani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Atena Hatami Fard

Position
Pharmacy student at Tabriz University of Medical Sciences

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Bachelor

Other areas of specialty/work
Medical Pharmacy

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No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz

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a.hatamifardddd@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Demographic data and main outcomes will be shared.

When the data will become available and for how long

Data files will become available 6 months after publication.

To whom data/document is available

It will be only available for people working in academic institutions.

Under which criteria data/document could be used

All of the data can be freely used if the citation is appropriately considered .

From where data/document is obtainable

The applicants will be referred to research Vice-chancellor .

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

All of the requested data should be mentioned in a application letter which will be sent to the Research Vice-chancellor of Tabriz University of Medical Sciences.

Comments