

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Effectiveness and safety of thalidomide in moderate COVID-19 pneumonia: A randomized clinical trial

Protocol summary

Study aim

Investigating the effectiveness and safety of thalidomide in patients with moderate pneumonia due to COVID-19

Design

Clinical trial with control group with parallel, randomized groups, phase 3 on 60 patients. The random number table was used for randomization

Settings and conduct

This study will be performed at Amin Hospital in Isfahan. Patients are randomly divided into two groups. The intervention group is treated with thalidomide tablets along with routine medications, and the control group receives only routine medications. Time to reach clinical improvement is determined in patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men 18 to 75 years old and women 50 to 75 years old admitted to the hospital, the percentage of oxygen saturation at the time of admission: 89-85% or the percentage of oxygen saturation 90-93% and the number of breaths per minute greater than or equal to 30, the clinical manifestation of which is consistent with COVID-19 pneumonia with a positive PCR test or corresponding HR-CT scan. Exclusion criteria: Chronic lung disease prior to study, multiple organ failure at admission

Intervention groups

Intervention group: Patients in this group are treated with 100 mg oral thalidomide tablets manufactured by Ibn Sina Company on a daily basis for up to fourteen days. These drugs were administered along with hydroxichloroquine tablets 200 mg two times daily for 5 days. Control group: patients are treated with hydroxichloroquine tablets 200 mg two times daily for 5 days.

Main outcome variables

The time to reach clinical recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200428047232N1**

Registration date: **2020-07-05, 1399/04/15**

Registration timing: **retrospective**

Last update: **2020-07-05, 1399/04/15**

Update count: **0**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Samane pourajam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3332 2986

Email address

s_pourajam@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness and safety of thalidomide in moderate COVID-19 pneumonia: A randomized clinical trial

Public title

Effect of Thalidomide in Covid 19 pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-75 year old men and 50-75 year old women admitted in hospital Percentage of oxygen saturation at the time of admission: 89-85% (provided it is modified with Nasal auxiliary oxygen to more or equal to 90%) or oxygen saturation percentage of 90-93% and the number of breaths per minute more or equal to 30 Clinical manifestations associated with COVID-19 pneumonia with positive PCR test or HR-CT scan

Exclusion criteria:

Previous Chronic lung disease Multi-organ failure at admission

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.

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 Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2020-04-17, 1399/01/29

Ethics committee reference number

IR.MUI.MED.REC.1399.048

Health conditions studied

1

Description of health condition studied

Pneumonia caused by Coronavirus 2019, COVID19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Time to reach clinical recovery

Timepoint

Daily visit in the hospital every 8 hours by the physician

Method of measurement

Pulse oximetry device

Secondary outcomes

1

Description

28 days survival rate

Timepoint

Weekly up to 4 weeks from the time of hospitalization to 4 weeks after discharge

Method of measurement

Telephone call

Intervention groups

1

Description

Intervention group: Patients in this group are treated with 100 mg oral thalidomide tablets manufactured by Ibn Sina Company on a daily basis for up to fourteen days. These drugs are administered along with hydroxichloroquine tablets 200 mg two times daily for 5 days.

Category

Treatment - Drugs

2

Description

Control group: patients are treated with hydroxichloroquine tablets 200 mg two times daily for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Samane pourajam

Street address

No. 2, Ebne Sina Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8137866515

Phone

+98 31 3445 9009

Email

Spourajam@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

haghjoo.sh@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Samane Pourajam

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Esfahan

Province

Isfahan

Postal code

8137866515

Phone

+98 31 3337 7986

Email

Spourajam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samane Pourajam

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Province

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Email

Spourajam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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

All potential data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments