Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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 Nazal 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
Isfehan
Postal code
۸۱۳۷۸۶۶۹۱۵
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 oximetery 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
Isfehan
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
Isfehan
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
Isfehan
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
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
City
Esfahan
Province
Isfehan
Postal code
8137866515
Phone
+98 31 3337 7986
Email
Spourajam@gmail.com

Person responsible for updating data

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
Isfehan

Postal code
8137866515

Phone
+98 31 3337 7986

Email
Spourajam@gmail.com

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