Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The efficacy and safety of Thalidomide in severe Covid19 pneumonia: Arandomized controlled clinical trial

Protocol summary

Study aim
The efficacy of Thalidomide in severe Covid19 pneumonia

Design
This study is a two arm parallel group clinical trial that will be done in Khorshid hospital. Randomization is done through block method. Sample size of this study is 60 patients that divided equally into two groups. Both groups treat with the same method, except the case group that receive thalidomide 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 Khorshid hospital. According to inclusion and exclusion criteria, patients are randomly divided into 2 grups. Both groups receive the same treatment. Trial group will be received thalidomide tablet daily until 14 days.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- 18-75 year old men and 50-75 year old women admitted in hospital 2-Spo2 less than 85% in admission 3-Clinical symptoms and signs compatible with COVID19 infection and positive PCR test or lung HRCT abnormalities compatible with COVID19 pneumonia 4-No need to intubation in first 24 hour of admission 5-No multiorgan failure at presentation 6- No shock state at presentation 7- Obtained informed consent Exclusion criteria: 1. Hepatic failure (Child Pugh score ≥ C, AST> 5 times of the upper limit normal) 2. Severe renal dysfunction (GFR less than 30cc per min)

Intervention groups
Both case and control group receive hydroxychloroquine tablet 100 mg BD for 5 days, acetaminophen codeine and syrup Diphenhydramine for symptom control, Antibiotics depend on physician choice (Ceftriaxone, Azithromycin, Vancomycin), Amp Enoxaparin 40 mg SC daily during hospitalization and Amp Methylprednisolone 50 mg IV daily for 7 days. trial group receive thalidomide tablet 100 mg for 14 days.

Main outcome variables
Time to clinical recovery, Intubation rate, Time to intubation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170207032444N3**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-17, 1399/01/29**
Update count: **0**

Registration date
2020-04-17, 1399/01/29

Registrant information

Name
Mehrzad Salmasi

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-15, 1399/01/27

Expected recruitment end date
2020-06-16, 1399/03/27

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy and safety of Thalidomide in severe Covid19 pneumonia: Arandomized controlled clinical trial

Public title
Thalidomide in COVID19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-75 year old men and 50-75 year old women admitted in hospital Spo2 less than 85% in admission Clinical symptoms and signs compatible with COVID19 infection and positive PCR test or lung HRCT abnormalities compatible with COVID19 pneumonia No need to intubation in first 24 hour of admission No multiorgan failure at presentation No shock state at presentation Obtained informed consent
Exclusion criteria:
Hepatic failure (Child Pugh score ≥ C, AST> 5 times of the upper limit normal) Severe renal dysfunction (GFR less than 30cc per min)
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
Block randomization will be done. We use random allocation service for randomization. There is no allocation concealment.
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 Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib street
City
Isfahan
Province
Isfehan
Postal code
8158177356
Approval date
2020-04-10, 1399/01/22
Ethics committee reference number
http://ethics.research.ac.ir/IR.MUI.MED.REC.1399.027

Health conditions studied

1

Description of health condition studied
COVID19
ICD-10 code
U07.1
ICD-10 code description
disease diagnosis of COVID-19 confirmed by laboratory testing.

Primary outcomes

1

Description
efficacy of Thalidomide in severe Covid19 pneumonia
Timepoint
Daily until discharge and then weekly until 28 days
Method of measurement
history, pulse oximetry, sphygmomanometer

Secondary outcomes

1

Description
28 days survival rate
Timepoint
daily until discharge and then weekly until 28 days
Method of measurement
history

Intervention groups

1

Description
Intervention group: Tab Thalidomide (Talidex) from Alan pharmaceuticals, daily until 14 days. Both case and control group will be received hydroxychloroquine tablet 100 mg BD, methylprednisolon 50 mg IV, antibiotic depend on physician choice (Ceftriaxone, Azithromycin, Vancomycin), Syrup Diphenhydramine and

acetaminophen codeine for symptom control and amp Enoxaparin 40 mg SC daily during hospitalization.

Category

Treatment - Drugs

2

Description

Control group: this group doesnt receive extra drugs. Both groups receive tab hydroxychloroquine 200 mg BID for 5 days, Tab Acetaminophen Codeine and syrup diphenhydramine for symptom control, Antibiotics depend on physician choice (Ceftriaxone, Azithromycin, Vancomycin), Amp Enoxaparin 40 mg SC daily during hospitalization and amp Methylprednisolone 50 mg IV daily for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorshid hospital

Full name of responsible person
Ramin Sami

Street address
Ostandari street

City
Isfahan

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Postal code
1234567891

Phone
+98 31 3222 2127

Email
khorshid@mui.ac.ir

Web page address
https://nour.mui.ac.ir/fa/Contact

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjooy Javanmard

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Daneshgah street

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8174673461

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
deputy minister of technology research

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
Farzane Ashrafi

Position
Associate Professor of Hematology and Oncology

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Position
Associate Professor of Hematology and Oncology

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
no more informations

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
No - There is not 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
not shared

When the data will become available and for how long
not shared

To whom data/document is available
not shared

Under which criteria data/document could be used
not shared

From where data/document is obtainable
not shared

What processes are involved for a request to access data/document
not shared

Comments