

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 $\geq$ 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

Country

Iran (Islamic Republic of)

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+98 31 3263 0366

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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 $\geq$ C, AST> 5 times of the upper limit normal) Severe renal dysfunction (GFR less than 30cc per min)

AgeFrom **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 committees1**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

Isfahan

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 studied1**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 outcomes1**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 outcomes1**Description**

28 days survival rate

Timepoint

daily until discharge and then weekly until 28 days

Method of measurement

history

Intervention groups1**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 doesn't 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

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<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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8174673461

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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****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Contact

Name of organization / entity
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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