

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Aug 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)

##### Phone

+98 31 3263 0366

##### Email address

m.salmasi@resident.mui.ac.ir

##### 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)

**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**

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 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 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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

1234567891

**Phone**

+98 31 3222 2127

**Email**

khoshid@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

**Street address**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

farzane ashrafi

**Position**

Associate Professor of Hematology and Oncology

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Subspecialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mehrzad Salmasi  
**Position**  
Assistant professor of internal medicine, Isfahan university of medical sciences  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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mehrzad\_salmasi@yahoo.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

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