

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 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

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+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

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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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

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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**