

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### A clinical trial to evaluate the therapeutic effects of thalidomide in patients with COVID-19 infection

#### Protocol summary

##### Study aim

Determining the therapeutic effects of thalidomide in patients with pneumonia caused by Covid 19

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 66 patients that will use Balanced block randomization method for randomization

##### Settings and conduct

Patients with Covid 19 pneumonia admitted to Amir Al-Momenin Hospital of Arak city will be randomly divided into intervention and control groups after entering the study. The intervention group will receive thalidomide and the control group will receive placebo. Blinding in this study will be done using a placebo drug of the same shape and color as the main drug and patients, clinical caregiver and outcome assessor will not be aware of the study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: onset of symptoms less than 10 days, lymphocytes less than 1000, CRP more than 1.5 times normal, Covid 19 positive pcr test, less than 93% oxygen saturation, respiratory rate less than 24 , CT scan findings in favor of infection To Covid 19. exclusion criteria: history of chronic disease, pregnancy, lactation, prone to pregnancy, ocp consumption, liver enzymes more than 5 times normal

##### Intervention groups

66 patients will be divided into two groups of 33 patients. In both groups, standard and recommended drugs in the protocol of the Ministry of Health and support measures for patients will be applied simultaneously, but in the intervention group, in addition to the drugs of the protocol of the Ministry, oral thalidomide at a dose of 100 mg for 14 days (every night) Will be prescribed. The control group will also receive oral placebo for 14 days every night.

##### Main outcome variables

Duration of hospitalization, death rate, blood oxygen

saturation, radiological changes of the lungs, laboratory tests

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110423006257N3**

Registration date: **2021-04-03, 1400/01/14**

Registration timing: **prospective**

Last update: **2021-04-03, 1400/01/14**

Update count: **0**

##### Registration date

2021-04-03, 1400/01/14

##### Registrant information

##### Name

Abdollahatif Moini

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1221 5812

##### Email address

dr.moini@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-09, 1400/01/20

##### Expected recruitment end date

2021-07-11, 1400/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A clinical trial to evaluate the therapeutic effects of thalidomide in patients with COVID-19 infection

**Public title**  
Thalidomide effects in COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Duration of the symptoms less than 10 days Lymphocyte count less than 1000 per microliter Quantitative CRP more than 1.5 times normal Positive pcr test of covid 19 O2 sat less than 93% Respiratory rate less than 24 Chest CT scan findings compatible with COVID-19 Pneumonia  
**Exclusion criteria:**  
History of chronic disease Pregnant women, lactating women , sexually active premenopausal women Loss of consciousness Liver enzymes more than 5 times normal

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **66**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Balanced block randomization is used as a randomization method. Patients are divided into two groups using the above method. Therefore, six four-part combinations of intervention groups A and B are as follows : AABB, ABAB, ABBA, BBAA, BABA, BAAB. Then we assign them from the number one to six and with the table of random numbers from the right side of the selected number, move in order and select each of the numbers 1 to 6 of the above combination that appears, and the people who agree to participate in Study, fall into study groups. The allocation concealment will also be maintained in this method and the order of the quadruple compounds will also be completely hidden.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, the patients are randomly assigned to different groups and physicians. The physicians, patients , nurses, primary investigators, and also researchers who collect clinical data and researchers who evaluate the treatment response will be blinded to the patient groups and treatment protocol

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Arak University of Medical Sciences  
**Street address**  
Payambar-e-azam Complex, Sardasht Town  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176341

**Approval date**  
2021-03-03, 1399/12/13

**Ethics committee reference number**  
IR.ARAKMU.REC.1399.343

**Health conditions studied**

**1**

**Description of health condition studied**  
Covid 19

**ICD-10 code**  
**ICD-10 code description**  
Covid 19

**Primary outcomes**

**1**

**Description**  
Radiological changes of the lung

**Timepoint**  
Before the intervention and two weeks after the intervention

**Method of measurement**  
Pulmonary computed topography scan

**2**

**Description**  
Death rate

**Timepoint**  
Before the intervention and two weeks after the intervention

**Method of measurement**  
observation

### 3

**Description**

Length of hospitalization

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

observation

### 4

**Description**

Blood oxygen saturation

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

Pulseoxymeter

## Secondary outcomes

### 1

**Description**

Complete blood count

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

Paraclinical

### 2

**Description**

Erythrocyte sedimentation rate

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

Paraclinical

### 3

**Description**

Interleukin 6

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

Paraclinical

### 4

**Description**

Creatine phosphokinase

**Timepoint**

Before the intervention and two weeks after the intervention

**Method of measurement**

Paraclinical

## Intervention groups

### 1

**Description**

Intervention group: In this group, in addition to the standard drugs recommended in the protocol of the Ministry of Health and supportive measures for patients, thalidomide (Lipomed-Swiss), in a dose of 100 mg, will be administered orally for 14 days (every night).

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In this group, standard and recommended drugs are prescribed for patients in the protocol of the Ministry of Health and supportive measures, and they receive placebo drug, both in color and shape with the main drug, for 14 days (every night).

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Amir al-momenin hospital

**Full name of responsible person**

Abdolatif Moeini

**Street address**

Payambar-e-azam Complex, Sardasht Town

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Phone**

+98 86 3417 3639

**Email**

research@arakmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Street address**

Payambare azam complex, Sardasht Town

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Phone**

+98 86 3417 3639

**Email**

research@arakmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Abdollatif Moini

**Position**

pulmonologist, Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Iran Internal Medicin Department of Amir-al-momenin Hospital

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 1222 5202

**Fax**

**Email**

dr.moini@arakmu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Abdollatif Moini

**Position**

pulmonologist, Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Iran Internal Medicin Department of Amir-al-momenin Hospital

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 1222 5202

**Fax**

**Email**

dr.moini@arakmu.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Abdollatif Moini

**Position**

pulmonologist, Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Iran Internal Medicin Department of Amir-al-momenin Hospital

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 1222 5202

**Fax**

**Email**

dr.moini@arakmu.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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