

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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)

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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

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

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Contact

Name of organization / entity

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Full name of responsible person

Dr. Abdollatif Moini

Position

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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