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
Abdollatif Moini

Name of organization / entity
Arak University of Medical Sciences

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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
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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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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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