

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effect of Thalidomide on moderate COVID-19 pneumonia

Protocol summary

Study aim

Effect of Thalidomide on moderate COVID-19 pneumonia

Design

Clinical trial with control group with parallel groups, phase 2-3 on 100 patients

Settings and conduct

This study is performed in Taleghani Hospital in Tehran on patients with moderate pneumonia caused by Covid-19. Patients will be treated with thalidomide or placebo tablets and the rate of recovery and death will be recorded and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definitive laboratory results based on Covid-19, radiographic results indicating the presence of injury and lung infection, less than 5 days have passed since the confirmation of the disease, moderate disease severity Exclusion criteria: pregnancy, lactation, receiving thalidomide or other experimental drugs related to the treatment of Covid-19 in the period before the inclusion of the study

Intervention groups

Intervention group: Patients in this group will receive 100 mg thalidomide tablets orally for 14 days in addition to other routine treatments for pneumonia caused by Covid-19. Patients' recovery rate as well as their mortality will be measured and evaluated. Control group: Patients in this group will receive placebo pills for 14 days in addition to routine treatments for pneumonia caused by Covid-19, and the patients' recovery rate as well as their mortality will be measured and evaluated.

Main outcome variables

Recovery rate and mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N5**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Thalidomide on moderate COVID-19 pneumonia

Public title

Thalidomide and moderate COVID-19 pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive laboratory results for Covid-19 Radiographic

results of lung injury and infection Less than 5 days have passed since the confirmation of the infection Moderate disease severity based on the World Health Organization classification criteria

Exclusion criteria:

Pregnancy Breastfeeding Receive thalidomide or other experimental drugs related to the treatment of Covid-19 within one month prior to enrollment Existence of a history of thromboembolism unrelated to recent Covid-19 disease History of interstitial lung disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Daneshgah Ave., Tehran

City

Tehran

Province

Isfahan

Postal code

8174673461

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.SBMU.MSP.REC.1399.684

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Complete clinical recovery time

Timepoint

After interventions

Method of measurement

Examination and clinical signs

2

Description

Mortality rate

Timepoint

After interventions

Method of measurement

Patients' records

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive 100 mg thalidomide tablets made by Kobel Daru Company orally for 14 days along with other routine treatments for pneumonia caused by COVID-19, such as antibiotics and fluid therapy. Patients' recovery rate as well as their mortality will be measured and evaluated.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive placebo tablets for 14 days in addition to routine treatments for pneumonia caused by Covid-19, such as antibiotics and fluid therapy and the patients' recovery rate as well as their mortality will be measured and evaluated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani hospital

Full name of responsible person

Mehdi Mohammadsharifi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Shahid Beheshti University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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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

Shahid Beheshti 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

Ghasem Mohammadsharifi

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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 data after the individuals are unidentified can be shared

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

Website of the Research Committee of Shahid Beheshti University of Medical Sciences

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