Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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
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Iran (Islamic Republic of)
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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

Isfehan

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
MehdiMohammadsharifi

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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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Person responsible for updating data

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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