Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The evaluation of isotretinoin effects on treatment of COVID-19 infections

Protocol summary

Study aim
Evaluation of isotretinoin effects on Covid-19 disease
Design
This study is A phase 3; non-randomized single-blind clinical trial, 50 patients more than 18 years with positive Covid-19 test will be allocated to either intervention (isotretinoin and standard of care) or routine standard of care.
Settings and conduct
Patients with positive coronavirus infection are included in the study based on PCR and CT scan findings. The onset of symptoms is assessed based on the patient's history, initial imaging findings, and PCR. Patient symptoms including sore throat, dry cough, chills, diarrhea, fever, and other symptoms are recorded. Fifty patients are allocated to intervention and control groups. Twenty-five patients receive 20 mg of isotretinoin twice daily for 7 days along with the standard of care treatment. Other patients receive the standard of care according to the national guidelines. Preliminary data include CT scan findings, clinical signs (fever, fatigue, dry cough, anorexia, shortness of breath, purulent discharge), pulse oximetry findings, and arterial blood gas tests are recorded and analyzed.
Participants/Inclusion and exclusion criteria
Definite Covid-19 disease; older than 18 years; duration of disease less than 48 hours.
Intervention groups
Patients received either Isotretinoin along with the standard of care or standard of care alone according to the national guideline
Main outcome variables
Hypoxia; dyspnea; fever; shivering; cough; fatigue; nausea.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190624043993N3**
Registration date: **2020-07-23, 1399/05/02**
Registration timing: **prospective**

Last update: **2020-07-23, 1399/05/02**
Update count: **0**
Registration date
2020-07-23, 1399/05/02

Registrant information
Name
foroud shahbazi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 83 3426 6780
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2020-11-21, 1399/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of isotretinoin effects on treatment of COVID-19 infections

Public title
The evaluation of isotretinoineffects on treatment of COVID-19 infections
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive covid-19 test During first 48 hours of symptoms

Exclusion criteria:

Underlying hematologic disease Underlying liver disease Known allergy to Isotretinoin Pregnancy/lactation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commitee of Kermanshah University of Medical Sciences

Street address

The vice-chancellor for research and technology, Beheshti Ave, Kermanshah,

City

Kermanshah

Province

Kermanshah

Postal code

6719851351-833

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.KUMS.REC.1399.288

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Virus identified

Primary outcomes

1

Description

Clinical Cure

Timepoint

Seven and 14 days after treatment initiation.

Method of measurement

Clinical and laboratory evaluations.

2

Description

Virological cure

Timepoint

Day 7

Method of measurement

PCR

3

Description

ABG findings

Timepoint

Day 7

Method of measurement

Laboratory assessment

Secondary outcomes

1

Description

Radiological cure, organ dysfunction, death

Timepoint

Day 14

Method of measurement

Clinical and para-clinical data

2

Description

Organ dysfunction

Timepoint

Day 7

Method of measurement

Clinical and laboratory data

3

Description

Death

Timepoint

Day 28

Method of measurement

Observation

Intervention groups

1

Description
Intervention group: Patients with Covid-19 disease will receive 20 mg Isotretinoin twice daily along with the standard of care for 7 days
Category
Treatment - Drugs

2

Description
Control group: Patients with Covid-19 disease will receive the standard of care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi hospital
Full name of responsible person
Maria Shirvani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. Farid Najafi
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Behesti Blve, Vice chancellor for research and technology
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083-38370541
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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
Kermanshah 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
Kermanshah University of Medical Sciences
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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