

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 83 3426 6780

Email address

foroud08@gmail.com

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 isotretinoin effects 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 committee 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

Street address

Farabi Medical education center, Dolat-Abad Boulevard, Isar Square, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

988338264820

Phone

+98 83 8216 0700

Fax

+98 83 3826 4163

Email

maria_shirvani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Behesti Blve, Vice chancellor for research and technology

City

Kermanshah

Province

Kermanshah

Postal code

083-38370541

Phone

+98 83 3838 4185

Email

farid_n32@yahoo.com

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

Full name of responsible person

Foroud Shahbazi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of pharmacy, Parastar Blve, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

1673-67145

Phone

+98 83 3426 6780

Email

Foroud08@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

ALI akrami

Position

RESIDENT

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery
Street address
School of medicine, Parastar Blve, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
1673-67145
Phone
+98 83 3426 6780
Email
akramiali7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Foroud Shahbazi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of pharmacy, Parastar Blve, Kermanshah
City
Kermanshah

Province
Kermanshah
Postal code
1673-67145
Phone
+98 83 3426 6780
Email
Foroud08@gmail.com

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