

# 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

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##### 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  
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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