

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Determining the effect of skin test purified protein derivative (PPD) on the recovery process of patients with COVID 19 in patients with this disease

#### Protocol summary

##### Study aim

Determining the effect of skin test purified protein derivative (PPD) on the recovery process of patients with COVID 19 in patients with this disease

##### Design

Determining the effect of skin test purified protein derivative (PPD) on the recovery process of patients with COVID 19 in patients with this disease

##### Settings and conduct

After registering the patient's personal details, including name and surname, gender, age, weight, place of residence, occupation, the presence of underlying diseases and disease profile, randomly assigned to one of the two groups tested and controlled based on AB and randomized block design. BA. Is placed. The control group includes those who receive only the usual treatment with chloroquine and Lopinavir / Ritonavir, and the control group, in addition to the treatment with the above-mentioned common drugs, also performs ppd (purified protein derivative) testing for them. We inoculate one-tenth of a milliliter, and the assessment is performed by an infectious disease specialist through daily trials for patients and a CT scan of the chest on days 3, 0, and 7, and a corona test on days 14-7 for patients to relieve fever.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: All patients diagnosed with covid-19. Output criteria: Patients with respiratory distress - which includes 1. Spo2 <60% 2. Severe respiratory distress 3. Hemodynamic instability 4. Acid base disturbance 5. Severe Anemia Patients with liver problems - People with nervous system defects

##### Intervention groups

All patients diagnosed with covid-19

##### Main outcome variables

Faster and less complicated recovery in patients with covid 19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200414047070N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

##### Registration date

2020-04-21, 1399/02/02

##### Registrant information

##### Name

abdolah azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5331 4200

##### Email address

hadiazizi2323@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### Expected recruitment end date

2020-09-05, 1399/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Determining the effect of skin test purified protein derivative (PPD) on the recovery process of patients with COVID 19 in patients with this disease

## Public title

Effect of ppd on recovery of covid disease 19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having covid 19

### Exclusion criteria:

People with severe illness( . Spo<sub>2</sub><60%<sup>2</sup>. Severe respiratory distress<sup>3</sup>. Hemodynamic instability<sup>4</sup>. Acid base disturbance<sup>5</sup>. Severe Anemia) People with defective immune systems Liver disease

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

After registering the patient's personal details, including name and surname, gender, age, weight, place of residence, occupation, the presence of underlying diseases and disease profile, randomly assigned to one of the two groups tested and controlled based on AB and randomized block design. BA.

## 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

Ethics committee of fasa University of Medical Sciences

##### Street address

Daneshgah

##### City

fasa

##### Province

Fars

## Postal code

7461686688

## Approval date

2020-04-18, 1399/01/30

## Ethics committee reference number

IR.FUMS.REC.1399.004

## 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

Having covid 19

#### Timepoint

3-7-14

#### Method of measurement

Negative test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: People with covid 19 Patients after accidental registration of personal information including name and surname, gender, age, weight, place of residence, job, the presence of underlying diseases and disease profile in one of the two intervention groups and Control based on AB and BA random block design. In addition to treatment with the common drugs Chloroquine and Lopinavir / Ritonavir, the intervention group (PPd (purified protein derivative) is also performed for them in the intervention group. We evaluate and evaluate by an infectious disease specialist through daily tests for patients and CT Scan of the chest on days 0, 3 and 7, and Corona testing on days 7 and 14 for patients to relieve fever

#### Category

Treatment - Drugs

### 2

#### Description

Control group: People with Covid 19 Patients after random registration of personal information including name and surname, gender, age, weight, place of

residence, occupation, the presence of underlying diseases and disease profile randomly in one of the two groups tested And control based on AB and BA random block design. They are only routinely treated with chloroquine and Lopinavir / Ritonavir, and are evaluated by an infectious disease specialist through daily tests for patients and CT Scan of the chest on days 0, 3 and 7, and Corona testing on days 7 and 14 for patients, fever relief, face Accept.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Vali Asr Hospital

**Full name of responsible person**

Dr.Jalal Karimi

**Street address**

Jomhori aslami

**City**

fasa

**Province**

Fars

**Postal code**

7461837513

**Phone**

+98 71 5331 4201

**Fax**

+98 71 5335 2590

**Email**

Hadiazizi2323@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr.Mojtaba Farjam

**Street address**

Daneshgah

**City**

fasa

**Province**

Fars

**Postal code**

7461686688

**Phone**

+98 71 5335 0994

**Email**

FARJAM.MD@GMAIL.COM

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Fasa 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**

Fasa University of Medical Sciences

**Full name of responsible person**

Abdolah Azizi

**Position**

Head of Non-Communicable Diseases

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Jomhore

**City**

Fasa

**Province**

Fars

**Postal code**

7461837513

**Phone**

+98 71 5331 4200

**Fax**

+98 71 5335 2590

**Email**

hadiazizi2323@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr.jalal karimi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Jomhori Aslami

**City**

fasa

**Province**

Fars

**Postal code**

7461837513

**Phone**

+98 71 5335 9600

**Email**

Jalalmd7@gmail.com

**Phone**

+98 71 5331 4200

**Fax**

+98 71 5335 2590

**Email**

hadiazizi2323@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Abdolah Azizi

**Position**

Head of Non-Communicable Diseases

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Jomhore

**City**

Fasa

**Province**

Fars

**Postal code**

7461837513

**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**

Not applicable