

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of naproxen on the healing process of patients with COVID-19

#### Protocol summary

##### Study aim

The effect of naproxen on the healing process of COVID-19 patients

##### Design

This double-blind clinical trial study has an intervention group and a control group with parallel and randomized groups, with a sample size of 80. A phase 2 study with block randomization.

##### Settings and conduct

The place of this study is in Ayatollah Taleghani Hospital in Abadan. In the patient control group, standard drugs use the national protocol + placebo (in terms of appearance and color similar to naproxen 500 mg every 12 hours for 5 days). In the intervention group, standard drugs of the national protocol + naproxen 500 mg every 12 hours are used for 5 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patients that have positive PCR test of nasopharyngeal sample or have positive CT Scan Having consent to participate in the intervention  
Exclusion criteria: pregnant or breast feeding women  
Those taking losartan and captopril. Those with a history of intestinal ulcers or gastrointestinal bleeding. Children under 14 years

##### Intervention groups

Control group: Standard drugs of the national protocol (hydroxychloroquine sulfate 200mg, two single-dose tablets (Tehran Daru) , two single-dose tablets (Pars), Kaletra tablets (Lupinavir / Ritonavir) every 12 hours 2 tablets 50/200)+ A placebo every 12 hours (in terms of appearance and color similar to 500 mg naproxen).  
Intervention Group: Standard Protocol Drugs For 5 days(Hydroxychloroquine Sulfate 200mg Two Single Dose tablets (Tehran Daroo) , Kaletra tablets (Lupinavir / Ritonavir) (Indian Ritcomum) every 12 hours, 2 tablets 50/200) + Naproxen 500 mg every 12 hours (Pars Daru) For 5 days

##### Main outcome variables

The recovery process of patients with Covid 19 (improvement of fever, chills, cough and night sweats)

#### General information

##### Reason for update

Edit publication list and date of recruitment

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200324046850N3**

Registration date: **2020-03-30, 1399/01/11**

Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**

Update count: **2**

##### Registration date

2020-03-30, 1399/01/11

##### Registrant information

###### Name

Sara Mobarak

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5326 7800

###### Email address

s.mobarak@abadanums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of naproxen on the healing process of patients with COVID-19

#### Public title

The effect of naproxen on the healing process of patients with COVID-19

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

COVID-19 patients that have positive PCR test of nasopharyngeal sample or have positive CT Scan Having consent to participate in the intervention

##### Exclusion criteria:

pregnant or breast feeding women Those taking losartan and captopril. Those with a history of intestinal ulcers or gastrointestinal bleeding. Children under 14 years

#### Age

From **15 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, block randomization was performed using block size: 6. Allocation sequence and concealment codes are generated by www.sealedenvelope.com. The closed envelope method was used to hide the allocation sequence.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Participants and researchers in this study are blind, and the placebo used in the control group is the pill, which is similar in appearance and color to naproxen.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Abadan School of Medical Sciences

###### Street address

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

#### City

Abadan

#### Province

Khouzestan

#### Postal code

631911154

#### Approval date

2020-03-18, 1398/12/28

#### Ethics committee reference number

IR.ABADANUMS.REC.1398.115

### Health conditions studied

#### 1

##### Description of health condition studied

corona virus disease

##### ICD-10 code

U07.2

##### ICD-10 code description

COVID-19, virus not identified

### Primary outcomes

#### 1

##### Description

Time to clinical improvement defined as start of taking medication time to the next 28 days.

##### Timepoint

The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

##### Method of measurement

Medical record

### Secondary outcomes

#### 1

##### Description

Duration of hospitalization

##### Timepoint

Time of discharge

##### Method of measurement

Number of hospital days

#### 2

##### Description

Duration of stay at ICU

##### Timepoint

Daily

##### Method of measurement

Number of days of hospitalization in ICU

#### 3

##### Description

Adverse events

**Timepoint**

Time of discharge

**Method of measurement**

Medical record

**4****Description**

laboratory variables (CBC, CRP, BUN, Cr, AST, ALT, ALK-ph, ESR, CPK)

**Timepoint**

The beginning of the study and the time of discharge

**Method of measurement**

Medical record

**5****Description**

Cough

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

Clinical observation and examination

**6****Description**

shortness of breath

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

Clinical observation and examination

**7****Description**

Fatigue

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

Clinical observation and Interview with the patient

**8****Description**

Diarrhea

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

Interview with the patient

**9****Description**

Body pain

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

Interview with the patient

**10****Description**

The patient's condition is based on inpatient or outpatient

**Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

**Method of measurement**

seven category ordinal scale

**Intervention groups****1****Description**

Control group: Standard drugs of the national protocol (hydroxychloroquine sulfate 200mg, two single-dose tablets (Tehran Daru) , two single-dose tablets (Pars), Kaletra tablets (Lupinavir / Ritonavir) every 12 hours 2 tablets 50/200)+ A placebo every 12 hours (in terms of appearance and color similar to 500 mg naproxen).

**Category**

Treatment - Drugs

**2****Description**

Intervention Group: Standard Protocol Drugs For 5 days (Hydroxychloroquine Sulfate 200mg Two Single Dose tablets (Tehran Daroo) , Kaletra tablets (Lupinavir / Ritonavir) every 12 hours, 2 tablets 50/200) + Naproxen 500 mg every 12 hours (Pars Daru) For 5 days

**Category**

Treatment - Drugs

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

Ayatollah Taleghani Hospital

**Full name of responsible person**

Sara Mobarak

**Street address**

Ayatollah Taleghani Hospital. University Blvd. Nurse Square. Abadan city

**City**

Abadan

**Province**

Khuzestan

**Postal code**

631911154

**Phone**

+98 61 5338 4004

**Email**

s.mobarak@abadanums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

Sara Mobarak

**Street address**

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

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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**

Abadan 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**

Abadan University of Medical Sciences

**Full name of responsible person**

Sara Mobarak

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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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 can be shared after the participants in the study

are unrecognizable.

### **When the data will become available and for how long**

The data access period after printing the article

### **To whom data/document is available**

The data in this study will be available to researchers working at academic and scientific institutions, as well as the Food and Drug Administration.

### **Under which criteria data/document could be used**

- Any analysis can be done with the consent of the main researcher.

### **From where data/document is obtainable**

s.mobarak@abadanums.ac.ir

### **What processes are involved for a request to access data/document**

-The researcher or pharmaceutical company can send their request to the academic email after sending the documents to confirm their original identity. The project manager will then provide the requested information to the researcher or pharmaceutical company after ensuring the accuracy of the submitted documents after a period of one week.

### **Comments**