

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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		Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.	
Public title	The effect of naproxen on the healing process of patients with COVID-19	City	Abadan
Purpose	Treatment	Province	Khouzestan
Inclusion/Exclusion criteria		Postal code	631911154
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	Approval date	2020-03-18, 1398/12/28
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	Ethics committee reference number	IR.ABADANUMS.REC.1398.115
Age	From 15 years old	Health conditions studied	
Gender	Both	1	
Phase	3	Description of health condition studied	
Groups that have been masked		corona virus disease	
	- Participant - Investigator	ICD-10 code	
Sample size	Target sample size: 80	U07.2	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
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.	COVID-19, virus not identified	
Blinding (investigator's opinion)	Double blinded	Primary outcomes	
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.	1	
Placebo	Used	Description	
Assignment	Parallel	Time to clinical improvement defined as start of taking medication time to the next 28 days.	
Other design features		Timepoint	
Secondary Ids		The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day	
empty		Method of measurement	
Ethics committees		Medical record	
1		Secondary outcomes	
Ethics committee		1	
Name of ethics committee		Description	
Ethics Committee of Abadan School of Medical Sciences		Duration of hospitalization	
Street address		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

Khouzestan

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.
City
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Province
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Postal code
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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
Street address
Abadan School of Medical Sciences, Beginning of the
30 meters Ave, Zolfaghari street, Abadan city.

City
Abadan
Province
Khouzestan
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631911154
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Sara Mobarak
Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Email

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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