Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Sep 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
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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
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.
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Postal code
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Phone
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Email
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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.
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Person responsible for scientific inquiries

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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
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Person responsible for updating data

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Position
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Infectious diseases
Street address
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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