Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the role of naproxen as adjunctive therapy with standard therapies and its efficacy in the early improvement and reduced mortality rate of COVID-19 patients

Protocol summary

Study aim
Evaluation of the role of naproxen as adjunctive therapy with standard therapies and its efficacy in the early improvement and reduced mortality rate of COVID-19 patients

Design
In the blocking technique of simple randomization, blocks will be made in the form of quadruples in [ABAB] mode and the Patients are divided into two equal groups of intervention and control.

Settings and conduct
At the beginning (day zero) and the end of the treatment period (day 10), both groups of patients will be examined using radiological imaging and viral load determination in terms of clinical symptoms. The mortality rate and recovery time will also be recorded. To perform the virus-time PCR test, a pharyngeal swab will be taken using a swab and the virus transport medium (VTM) at the beginning of treatment (day zero) and the end (day 10) to perform tests. Molecular (gene extraction, cDNA synthesis and real-time PCR testing) will be used. Patients will be followed up for 30 to 60 days after starting treatment, and the effects of treatment and mortality will be recorded in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria; Patients who will be admitted for SARS-CoV-2 infection, Age over 18 years, the patient should be voluntary, the conscious consent form must be completed and signed by the patient or his companion. Exclusion Criteria; high creatinine and kidney problems, active gastrointestinal ulcers.

Intervention groups
Control group: A group of patients who will be treated according to the standard treatment provided in the latest national guide to COVID-19 disease. Intervention group: A group of patients who will also receive naproxen 500 mg tablets 3 times a day in addition to the standard treatment.

Main outcome variables
The aim of this study is investigation in the length of recovery period after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200410047009N1**
Registration date: **2020-04-26, 1399/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-26, 1399/02/07**
Update count: **0**

Registration date
2020-04-26, 1399/02/07

Registrant information

Name
Maryam Esghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 3014

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-13, 1399/01/25

Expected recruitment end date
2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the role of naproxen as adjunctive therapy with standard therapies and its efficacy in the early improvement and reduced mortality rate of COVID-19 patients

Public title

The effect of Naproxen in recovery and reducing mortality in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whose SARS-CoV-2 infection has been confirmed using PCR Age over 18 years The conscious consent form must be completed and signed by the patient or his companion The patient should participate in the research voluntarily

Exclusion criteria:

High creatinine and kidney problems In gastrointestinal ulcers Other conditions of contraindications to the use of Naproxen

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **101**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two equal groups of intervention and control by simple randomization and ABAB quadruple blocking method.

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.IUMS.REC.1399.001

Health conditions studied

1

Description of health condition studied

covid-19 disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Recovery in COVID-19 patients

Timepoint

At the beginning (day zero) and the end of the treatment period (day 10)

Method of measurement

Examination of clinical signs

2

Description

mortality rate in COVID-19 patients

Timepoint

At the end of treatment period

Method of measurement

The percentage of mortality rate in the study population

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of COVID-19 patients who will receive 500 mg Naproxen tablets 3 times a day for 10 days orally, in addition to the standard treatment provided in the latest national guide which the control

group receives.

Category

Treatment - Drugs

2

Description

Control group: A group of patients will be treated according to the standard treatment provided in the latest national COVID-19 guide:Two-drug regimen: Oseltamivirwith hydroxychloroquine / chloroquine- Three-Phase Diet: Oseltamivir with Hydroxychloroquine / Chloroquine and Lopinavir / RitonavirFour-Phase Diet:Oseltamivir with Hydroxychloroquine / Chloroquine and Lopinavir / Ritonavir and Ribavirin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated with Iran University of Medical Sciences

Full name of responsible person

Maryam Esghaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Esghaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Virology

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Person responsible for updating data

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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
Not applicable
Title and more details about the data/document
Information on the results of the use of naproxen
When the data will become available and for how long
The first access, 6 months after publishing the results
To whom data/document is available
For researchers working in academic institutions
Under which criteria data/document could be used
Physicians are allowed to use data to treat patients.
From where data/document is obtainable
Maryam Esghaei
What processes are involved for a request to access data/document
Receive the documents by sending an e-mail to Dr Maryam Esghaei.
Comments