

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

##### Phone

+98 21 8670 3014

##### Email address

esghaei.m@iums.ac.ir

##### 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: Oseltamivir with hydroxychloroquine / chloroquine- Three-Phase Diet: Oseltamivir with Hydroxychloroquine / Chloroquine and Lopinavir / Ritonavir Four-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

#### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 8770 3014

#### Email

esghaei.m@iums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Seyed Abbas Motevalian

#### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 8670 2503

### Email

research-m@iums.ac.ir

### 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

#### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,

#### City

Tehran

#### Province

Tehran

#### Postal code

14665354

#### Phone

+98 21 8670 3014

#### Email

esghaei.m@iums.ac.ir

## Person responsible for scientific 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

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

تهران، بزرگراه همت ج

**Phone**

+98 21 8670 3014

**Email**

esghaei.m@iums.ac.ir

**Person responsible for updating data****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

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۹۶۱۴۵۳۵

**Phone**

+98 21 8670 3014

**Email**

esghaei.m@iums.ac.ir

**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**