

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Dec 2021

### The role of Nimesulide in the treatment of COVID-19 infection

#### Protocol summary

##### Study aim

To study the effect of nimesulide in the treatment of COVID-19 pneumonia.

##### Design

Uncontrolled Longitudinal study, single-center, comprising 60 patients with COVID-19 infection

##### Settings and conduct

All the patients will receive nimesulide 100 mg twice daily and sucralfate suspension 10 ml twice daily for five days. Patients who have a raised CRP will be prescribed azithromycin 250 mg twice daily for five days. Those patients who have a raised D-dimers test (greater than 500) will be given enoxaparin in a dose of 40 mg subQ once daily for five days. All patients will have a baseline spO2 measured and a chest radiograph done that will be repeated after 5 days.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Participant is willing and able to give informed consent for participation in the study and agrees with the study protocol • Adults  $\geq$  12 years • Not previously diagnosed with COVID-19 infection or treated. Exclusion Criteria: • Participant is allergic to any of the study groups. • Participants with a contraindication to any of the drugs including: o Active bleeding o Recent Myocardial infarction (last three months) o Peptic ulcer disease • Already taking an NSAID or Nimesulide. • Inability to be followed up for the trial period

##### Intervention groups

Nimesulide is an anti-inflammatory drug that will be added to the treatment regimen of all patients with COVID-19 infection who are enrolled in the study and followed after five days.

##### Main outcome variables

The outcome will be measured in terms of a percent change in oxygen saturation, hospitalization, or death.

#### General information

##### Reason for update

##### Acronym

NICI

##### IRCT registration information

IRCT registration number: **IRCT20200723048178N1**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

##### Registration date

2020-07-28, 1399/05/07

##### Registrant information

###### Name

Ahmed Farhan

###### Name of organization / entity

Pakistan Institute of Medical Sciences

###### Country

Pakistan

###### Phone

+92 51 9261592

###### Email address

drfarhan992@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-28, 1399/05/07

##### Expected recruitment end date

2020-09-27, 1399/07/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The role of Nimesulide in the treatment of COVID-19 infection

##### Public title

nimesulide in COVID-19 infection

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The participant is willing and able to give informed consent for participation in the study and agrees with the study protocol Not previously diagnosed with COVID-19 infection or treated. Adults  $\geq$  12 years

### Exclusion criteria:

The participant is allergic to any of the study group  
Inability to be followed up for the trial period  
Already taking an NSAID or Nimesulide  
Participants with a contraindication to any of the drugs including Active bleeding, Recent Myocardial infarction (last three months), or Peptic ulcer disease

## Age

From **12 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

Uncontrolled longitudinal study

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shaheed Zulfiqar Ali Medical University

##### Street address

G-8/3

##### City

Islamabad

##### Postal code

46000

#### Approval date

2020-07-22, 1399/05/01

#### Ethics committee reference number

No.F.1-1//2015/ERB/SZABMU/605

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 infection

#### ICD-10 code

U07.2

#### ICD-10 code description

COVID-19

## Primary outcomes

### 1

#### Description

percent change in the oxygen saturation, hospitalization, or death.

#### Timepoint

1 week

#### Method of measurement

Oxygen saturation is measured via pulse oximeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Nimesulide 100 mg twice daily for five days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Safiya Medical Center

##### Full name of responsible person

Ahmed Farhan

##### Street address

Ali Akbar house, G-8 Markaz, Islamabad

##### City

Islamabad

##### Postal code

46000

##### Phone

+92 51 2331590

##### Email

drfarhan992@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shaheed Zulfiqar ali medical university

**Full name of responsible person**

Dr. Ahmed Farhan

**Street address**

G-8/2 Islamabad Capital Territory

**City**

Islamabad

**Postal code**

46000

**Phone**

+92 51 2331590

**Email**

emedz.net@gmail.com

**Web page address**

<https://www.emedz.net>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

ahmed farhan

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Shaheed Zulfiqar Ali Mdicl University

**Full name of responsible person**

Ahmed Farhan

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

House # 116, Jhelum Road, G-8/1 Islamabad

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### Person responsible for scientific inquiries

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

Shaheed Zulfiqar Ali Medical University

**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**

Shaheed Zulfiqar Ali Medical University

**Full name of responsible person**

Ahmed Farhan

**Position**

Assistant Professor

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**Web page 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

Not applicable

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Primary outcome

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

Data will be available for six months after its collection

### To whom data/document is available

Healthcare workers

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

Data may be requested via email

### From where data/document is obtainable

individuals can ask for it via the personal email of the investigator

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

Data may be available within a week after the request.

### Comments