Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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 ≥ 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 ≥ 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

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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

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emedz.net@gmail.com

Web page address
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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 Mdical University

Full name of responsible person
Ahmed Farhan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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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