

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

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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

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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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Ahmed Farhan

Position

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Person responsible for updating data

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Position

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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