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# Effect of the drug indomethacin in the treatment of COVID-19 patients

**Submission date**
19/11/2020

**Registration date**
20/11/2020

**Last Edited**
17/03/2021

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Infections and Infestations

[_] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

## Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Indomethacin has shown potent anti-viral properties against SARS-CoV-2 in the lab and against canine coronavirus. It is a well known anti-inflammatory drug. As the body's inflammatory response is responsible for patients progressing to severe disease, this drug may stop the virus from multiplying and calm the immune system. The aim of this study to assess the effectiveness of the drug at preventing mild and moderate patients progressing to severe disease.

Who can participate?
Patients aged 21 to 90 with COVID-19 who are in hospital

What does the study involve?
Participants are treated for 5 days with indomethacin two times a day along with a proton pump inhibitor drug. Standard care is also provided. The following drugs are not to be used: remdesivir, corticosteroids, and paracetamol. Participants are followed up for 14 days and are advised to return to the hospital if they have any problems.

What are the possible benefits and risks of participating?
Benefits may include a quick recovery from COVID-19. The drug has a good safety profile. There have been reports of gastrointestinal (digestive system) bleeding and nephrotoxicity (kidney damage) in higher doses than given in this study. Nevertheless, these will be monitored in the study.

Where is the study run from?
Indian Institute of Technology Madras (India)

When is the study starting and how long is it expected to run for?
July 2020 to January 2021

Who is funding the study?
Mr Kris Gopalakrishnan, Alumnus IIT Madras through the Indian Institute of Technology Madras (India)

Who is the main contact?
1. Dr Rajan Ravichandran
rajanr@iitm.ac.in
2. Prof. R. Krishna Kumar
rkkumar@iitm.ac.in

# Contact information

## Type(s)
Scientific

## Contact name
Prof Ramarathnam Krishna Kumar

## ORCID ID
https://orcid.org/0000-0003-4097-6385

## Contact details
Department of Engineering Design
Indian Institute of Technology Madras
Chennai
India
600036
+91 (0)9840225856
rkkumar@iitm.ac.in

## Type(s)
Scientific

## Contact name
Dr Rajan Ravichandran

## ORCID ID
https://orcid.org/0000-0002-3375-2060

## Contact details

MIOT Hospitals
4/112 Mount Poonamalle High Road
Sathya Nagar
Mannapakkam
Chennai
India
600089
+91 (0)9840375892
rajanr@iitm.ac.in

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

CR/20-21/ED/208/ALUM/002553

# Study information

## Scientific Title

An academic multicentre open-label single-arm study to record the efficacy of indomethacin among confirmed COVID-19 patients with mild and moderate symptoms

## Study objectives

Indomethacin is effective in the treatment of mild and moderate COVID-19 patients and decreases the hospitalisation of these patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 03/08/2020, Institutional Ethics Committee, Narayana Medical College (Nellore 524003, India; +91 (0)8008086119; dean@narayanamedicalcollege.com), ref: NMC/Ethics/Project/006/2020
2. Approved 10/10/2020, Institutional Ethics Committee, Datta Meghe Institute of Medical Sciences (Sawangi (Meghe), Wardha - 442004, Maharashtra, India; +91 (0)7152 287701; icc.dmims@gmail.com), ref: DMIMS(DU)/IEC/2020-21/9034

## Study design

Multicenter interventional single-arm open-labelled trial and an academic retrospective study to act as control for comparison

## Primary study design

Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

## Interventions
1. Indomethacin 25 mg two times a day (or 75 mg SR once a day at the discretion of the treating physician) and a proton pump inhibitor 20 mg (or 40 mg at the discretion of the treating physician) for 5 days
2. Standard care as per the protocol of the hospital
3. The following drugs are not to be administered: remdesivir, corticosteroids, and paracetamol
4. Total duration of treatment: 5 days
5. Follow-up: 14 days
6. The patients are advised to return to the hospital if they have any problems

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Indomethacin, proton pump inhibitor

## Primary outcome(s)
Patients deteriorating to severe disease measured using the WHO Ordinal Scale for Clinical Improvement every day during the treatment and after the treatment on the sixth day

## Key secondary outcome(s))
1. Kidney function measured using urea and creatinine before the start of the treatment and after the treatment on the sixth day
2. Liver function measured using SGOT and SGPT before the start of the treatment and after the treatment on the sixth day
3. Inflammation measured using C-reactive protein before the start of the treatment and after the treatment on the sixth day

## Completion date
01/01/2021

# Eligibility

## Key inclusion criteria
1. Age 21 to 90 years
2. RT-PCR positive
3. Hospitalised patients
4. The case criteria for the study: LFT and KFT normal

## Participant type(s)
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Sex**
All

**Key exclusion criteria**
1. Hypersensitivity/allergy to drug
2. Gastritis
3. Recent heart attack
4. Severe asthma
5. Acute kidney Injury
6. Patients on immunosuppressants

**Date of first enrolment**
16/08/2020

**Date of final enrolment**
10/12/2020

# Locations

**Countries of recruitment**
India

**Study participating centre**
**Narayana Medical College**
Nellore
Nellore
India
524003

**Study participating centre**
**Datta Meghe Institute of Medical Sciences**
Sawangi (Meghe)
Wardha
India
442004

# Sponsor information

## Organisation

Indian Institute of Technology Madras

## ROR

https://ror.org/03v0r5n49

# Funder(s)

## Funder type

Other

## Funder Name

Mr Kris Gopalakrishnan, Alumnus IIT Madras through the Indian Institute of Technology Madras

# Results and Publications

### Individual participant data (IPD) sharing plan

The blood tests and CT scans are the data that will be stored and will be available on request from the Principal Investigator of the sites. The request can be sent to the respective centre's ethics committee, who will consider sharing the raw data based on legal and ethical considerations. Consent will be obtained from the participant and data will be anonymised to safeguard the privacy of the participants.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Preprint results | non-peer-reviewed results in preprint | 16/12/2020 | 17/03/2021 | No | No |
| Protocol file | | | 20/11/2020 | No | No |