Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

Efficacy and safety of oral indomethacin for treatment of covid 19 induced pneumonia

Protocol summary

Study aim
Evaluation of the time to clinical recovery in the case with indomethacin in moderate-intensity pneumonia caused by Corona 19 compared with the control group

Design
Randomized single blind, phase 3 clinical trial on 60 patients, The random number table was used for randomization

Settings and conduct
This study was performed in two hospitals, Noor and Amin, in Isfahan, on patients with moderate-intensity pneumonia caused by covid 19.

Participants/Inclusion and exclusion criteria
Inclusion criteria 18- to 75-year-olds with moderate-intensity pneumonia caused by Covid 19 whose disease has been proven on the basis of CT scan or PCR evidence and have signed a participation form. Exclusion criteria All people who are prohibited from taking indomethacin or similar compounds or who are likely to have severe side effects if taken indomethacin

Intervention groups
Patients with inclusion criteria in the intervention group, in addition to the usual treatment, are treated daily with indomethacin 75 mg slow-release tablets for 5 consecutive days. In the control group, placebo is added to the usual treatment for covid 19 infection.

Main outcome variables
Time to clinical recovery 14 days readmission Rate Time to intubation Intubation rate 28 days survival rate side effects caused by indomethacin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200427047215N1**
Registration date: **2020-05-05, 1399/02/16**
Registration timing: **prospective**
Last update: **2020-05-05, 1399/02/16**
Update count: **0**

Registration date
2020-05-05, 1399/02/16

Registrant information

Name
Ali Darakhshandeh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3777 2640

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alidarakhshandeh@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-08, 1399/02/19

Expected recruitment end date
2020-07-09, 1399/04/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of oral indomethacin for treatment of covid 19 induced pneumonia

Public title
Evaluation effect of Indomethacin for Covid19 infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 18 to 75 years old hospitalized Patient with

SpO2:85-89% on room air at admission (if correct with nasal O2 maximum 6 liter/min to SpO2>=90) Patients with SpO2: 90-93% and RR>=30 clinical compatible patients with positive RT-PCR test or consistent HRCT to covid19 pneumonia Sign the study participation form

Exclusion criteria:

Known hypersensitivity to indomethacin or any components of NSAIDs History of asthma, urticarial, or other allergic type reaction after taking aspirin or NSAIDs GFR less than 60ml/minute/1.7m2 Patients with active gastrointestinal bleeding The need for intubation in the first 24 hours of hospitalization Patients with multi organ failure Patients with shock state at admission Pregnant woman Lactating woman Patients with active peptic ulcer Consumption of NSAID on admission

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the random number table method is used for randomization.The randomization unit is also the individual.To read numbers, it is also from left to right.For concealment, the method of sequentially numbered, sealed, opaque envelopes is used.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients, the main researcher, the physician who visits patients daily for response to the treatment and examination of symptoms, and is responsible for collecting information, and the nursing staff are kept blind to the allocation of study groups.All patients are visited daily by one of the physicians of the treatment team who is in the process of intervention.However, the follow-up of the side effects of the drug and the evaluation of the course of treatment in patients will be performed by another physician, who is also in the general study constant.This physician will monitor the condition of patients at home for up to 4 weeks after discharge and will be completely blind.

Placebo

Used

Assignment

Other

Other design features

In this study, patients with admission conditions were divided into two groups. In addition to the usual treatment for coronavirus infection, the intervention group received 75 mg of indomethacin tablets daily for 5 consecutive days, but the control group received routine treatment for corona infection plus placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

No 566, 13 Alley, Saadat streat, Janbazan Blvd, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174797677

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.MUI.MED.REC.1399.045

Health conditions studied

1

Description of health condition studied

Pneumonia induced by covid19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Time to clinical recovery

Timepoint

Control clinical signs daily until discharge from the hospital

Method of measurement

Fever control with thermometer, oxygen saturation control with pulsoximetry

2

Description

14 days readmission after discharge.

Timepoint

Up to 14 days after discharge

Method of measurement

All patients will be given a contact number to notify them if they are hospitalized again. All patients will be

monitored by phone weekly for up to 4 weeks after the first day they are admitted.

3

Description
Time to intubation
Timepoint
Control of oxygen saturation, respiratory status every 6 hours during hospitalization
Method of measurement
If the patient needs intubation due to reduced oxygen saturation or increased respiration rate, the date of incubation will be recorded on a daily basis from the time of hospitalization.

Secondary outcomes

1

Description
Survival 28 days after hospitalization
Timepoint
From the first day of hospitalization to 28 days after hospitalization
Method of measurement
A questionnaire is used to measure survival. At the time of hospitalization, this questionnaire is completed daily by one of the researchers. After discharge, the patient's condition will be monitored weekly for up to 4 weeks after the first day of hospitalization.

Intervention groups

1

Description
Intervention group:Ŝlow release Indomethacin tablets, 75 mg daily for five days. Made by Aria Pharmaceutical Company
Category
Treatment - Drugs

2

Description
Control group: A placebo similar to indomethacin tablets is given daily for five days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Hospital
Full name of responsible person
Ali Darakhshandeh
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Hasht behesht Ave, Ostandari Ave
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Hezar Jarib Ave,Isfahan univercity of medical sciences
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Isfehan
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Email
isfahan.med@mui.ac.ir
Web page address
http://med.mui.ac.ir/
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences Vice Chancellor for Research and Technology
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
Esfahan University of Medical Sciences
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Ali Darakhshandeh
Position
Assistant professor
Latest degree
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participants' data is shared after it becomes unrecognizable
When the data will become available and for how long
Data access starts immediately after printing the results
To whom data/document is available

The data in this study are only available to medical researchers

Under which criteria data/document could be used

It is available for any analysis or use that aims to improve and progress in the treatment of covid19 infection

From where data/document is obtainable

Contact email address:alidarakhshandeh@yahoo.com
Phone call: 00989133817087

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

In case of requesting data for the study, the applicant must first introduce himself or herself and the relevant organization to determine the purpose of the data request and state for what purpose this data is used.After submitting the request, if the researchers of this study prove that the data of this study can advance the therapeutic goals, the information will be sent as long as the data remains confidential.This process takes two weeks.

Comments