Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2021

Evaluation of short-term effects of Celecoxib on clinical improvement of COVID-19 patients: A randomized clinical trial study

Protocol summary

Study aim

Evaluation of short-term effects of Celecoxib on clinical improvement of COVID-19 patients: A randomized clinical trial study

Design

Based on the treatment chart and matching of the studied individuals and in order to eliminate any confounding factor, receiving all kinds of main and complementary drugs and also the dose of the drug is referred to the instructions of the Ministry of Health, in treatment for patients with moderate disease. Patients admitted are divided into two general groups. During the treatment period, the variables raised in patients are evaluated.

Settings and conduct

The intervention group receive celecoxib about 100 mg twice daily and full dose of 200 mg twice daily for 7 days in addition to routine treatments. The control group receives only routine treatments. The income of the disease is divided into two groups: improvement of lung function, lack of progression of symptoms or becoming a severe condition of the disease.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Moderate pulmonary involvement 2. Shortness of breath, chest pain with or without fever 3. SpO2:90-93% 4. Age: 18-65 years 5. Existence of pneumonia 6. Patients with informed consent Exclusion criteria: 1. Patients under 18 or over 65 years old 2. Severe and advanced disease 3. Shock and critical illness 4. Taking certain medications 5. Pregnancy 6. Chronic diseases

Intervention groups

First/control group: 20 patients receiving routine therapy Second Group (40 patients receiving routine therapy+celecoxib) is divided into two subgroups (20 people in each group): A: received dose 200mg/day B: received dose of 400mg/day

Main outcome variables

1. CT imaging (Pulmonary infiltration, Peripheral GG, edema) 2. Respiratory factors (respiratory rate, Blood oxygen saturation, PaO2/FiO2) 3. Body temperature 4. Improvement of lung function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200907048644N1**
Registration date: **2020-10-04, 1399/07/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-04, 1399/07/13**
Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Roghayeh Sheervalilou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5817

Email address

sheervalilour@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of short-term effects of Celecoxib on clinical improvement of COVID-19 patients: A randomized clinical trial study

Public title

Celecoxib effects on COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects with COVID-19 in the second phase of the disease Shortness of breath, chest pain with or without fever equal to or greater than 38 'C Blood oxygen saturation (SpO2) between 90-93% Adult patients with COVID-19 with moderate pulmonary involvement and hospitalized in the general ward who have been diagnosed and confirmed with coronavirus by conventional diagnostic methods such as sequencing or qRT-PCR and CT (within 48 hours of admission) Age range of patients between 18-65 years Existence of pneumonia in lung CT scan with involvement of maximum 3 or 4 lung lobes or less than one third of the volume of each lobe or infection of one or two lobes with larger area Patients informed consent

Exclusion criteria:

Patients under 18 or over 65 years old Patients with severe and advanced disease are admitted to the intensive care unit Participate in another clinical trial Shock and critical illness (requires ventilator and organ failure) Patients with organ dysfunction such as renal failure and liver damage, patients with asthma Taking certain medications such as furosemide or Lasex, lithium, ACE2 inhibitors Pregnancy People with medical history such as high blood pressure, autoimmune diseases and ..

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **1**

Blood sample collection and respiratory swap

Randomization (investigator's opinion)

Randomized

Randomization description

Based on previous studies calculating the sample size for interventional studies, 60 adult patients with moderate COVID-19 (hospitalized in the general ward) are randomly divided into two groups by permutation block method. So that the two groups are matched to the variables of age and sex.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Dr. Hesabi

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2020-08-26, 1399/06/05

Ethics committee reference number

IR.ZAUMS.REC.1399.197

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Lung function (Pulmonary infiltration, GGO, Edema)

Timepoint

Every week

Method of measurement

CT Scan

2

Description

Respiratory Rate, SpO2, PaO2/FiO2

Timepoint

Every day

Method of measurement

Physical examination

3

Description
Body Temperature
Timepoint
Every day
Method of measurement
Thermometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 40 patients receiving routine + celecoxib treatments. This group is divided into two subgroups (20 people in each group):A dose received 200mg / day (in divided doses)B at a dose of 400mg / day (in divided doses)
Category
Treatment - Drugs

2

Description
Control group: 20 subjects with routine therapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Research Hospital, Zahedan
Full name of responsible person
Dr. Mohammad Kazem Momeni
Street address
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2

Recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available