

# 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. SpO<sub>2</sub>: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, PaO<sub>2</sub>/FiO<sub>2</sub>) 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**

Khalij Phars roundabout, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743111

##### **Phone**

+98 54 3329 5570

##### **Email**

drkazemmomeni@gmail.com

##### **Web page address**

<https://www.dr.saina.com/cn-hs-a69322fb2ffa4fb1b2ea462a57f9914b/%D8%A2%D8%AF%D8%B1%D8%B3-%D9%88-%D8%B4%D9%85%D8%A7%D8%B1%D9%87-%D8%AA%D9%84%D9%81%D9%86-%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86-%D8%B9%D9%84%DB%8C->

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%D8%A7%D8%A8%DB%8C%D8%B7%D8%A7%D9%84%D8%A8-%D8%B9-

%D8%B2%D8%A7%D9%87%D8%AF%D8%A7%D9%86/

#### 2

#### **Recruitment center**

##### **Name of recruitment center**

Bu-Ali Hospital, Zahedan

##### **Full name of responsible person**

Maliheh Metanat

##### **Street address**

Shohada round about, Shariati Avenue, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

17117

##### **Phone**

+98 54 3378 6182

##### **Email**

boali.hospital96@gmail.com

##### **Web page address**

<http://boali.zaums.ac.ir/>

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Dr. Nour Mohammad Bakhshani

##### **Street address**

Dr. Hesabi Rounabout, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743463

##### **Phone**

+98 54 3337 2151

##### **Email**

public@zaums.ac.ir

##### **Web page address**

<http://zaums.ac.ir/default.page>

#### **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

**Postal code**

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**Email**

ghaznavih@yahoo.com

**Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Roghayh Sheervalilou

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Molecular Medicine

**Street address**

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**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Roghayeh Sheervalilou

**Position**

Assistant Prof.

**Latest degree**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Habib Ghaznavi

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology

**Street address**

Dr. Hesabi roundabout, Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**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