

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the Effect of Trifluoperazin in Treatment of Patients with Confirmed 2019 Novel Coronavirus(COVID- 19): An Open-Label Randomized Clinical Trial

Protocol summary

Study aim

Evaluation the effect of Trifluoperazine in treatment of patients with confirmed COVID- 19

Design

Clinical trial with control group with parallel, Open labeled, Randomised

Settings and conduct

Clinical trials will be conducted at the Valiasr Medical-Educational Center affiliated to Birjand University of Medical Sciences on approved COVID-19 patients. Patients are treated in two groups. The study will be performed at the beginning of hospitalization.

Participants/Inclusion and exclusion criteria

Inclusion and exclusion criteria in study: Patients who have been confirmed with the Real Time PCR test for COVID-19 disease or patients who show evidence of lung involvement on CT scans. The desire to participate in the study Age over 12 years Hospitalization in the department dedicated to patients with COVID-19 Lack of confirmed allergy to triflurpazine Absence of liver disease Over 65 years of age if dementia-related psychosis is not present Lack of viral and bacterial infections Absence of pregnancy in women Patients with benign prostatic hyperplasia Patients with intestinal obstruction Patients with blood disorders and bone marrow disorders Patients with severe central nervous system weakness or coma

Intervention groups

Control group:Patients treated with hydroxychloroquine and, if necessary, according to the approved treatment protocol, kaletra and ribavirin are added to the treatment. Case group:In addition to treating hydroxychloroquine, trifluoperazine is given at a dose of 2 mg twice daily for 14 days. In this group, if necessary, according to the approved treatment protocol, Kaletra and ribavirin are added to the treatment.

Main outcome variables

Determination of therapeutic effects of trifluoperazine in

patients with COVID19: -Respiratory function of the lungs. -Reducing the patient's inflammatory responses. - Reduction of the patient's hospitalization period. -Reduce mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046992N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Kazem Dastjerdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 2639

Email address

dastjerdi1974@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-16, 1399/01/28

Expected recruitment end date

2020-07-18, 1399/04/28

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Trifluoperazin in Treatment of Patients with Confirmed 2019 Novel Coronavirus(COVID-19): An Open-Label Randomized Clinical Trial

Public title
Effect of Trifluoperazine in treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with laboratory-confirmed COVID 19 infection with Real Time PCR and patients with evidence of lung involvement in CT Scan Willing to provide informed consent Age older than 12 years. Patients admitted to specialized COVID-19 ward Patients without Known severe allergy to trifluoperazine perazin and other phenothiazines such as cholorphenothiazines Patients older than age 65 years are included if they do not suffer from Dementia-Related Psychosis
Exclusion criteria:
Patient With a Liver Disorder Patients with bacterial or viral infection Pregnant women Patients with benign prostatic hyperplasia (BPH) Patients with intestinal obstruction Patients with blood disorders or bone marrow failure Coma patients and patients with central nervous system weakness

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences , Ghafari Street, Birjand,

City

birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2020-04-08, 1399/01/20

Ethics committee reference number

IR.BUMS.REC.1399.004

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description

Determining the efficacy of trifluoperazine in improving the Clinical manifestations of patients with confirmed COVID-19 infection by recording the patient's clinical parameters including 7 clinical parameters of respiration number, Blood Oxygen Saturation, oxygen support, temperature, heart rate, systolic blood pressure and Awareness level, assessment of lung involvement with Chest CT-Scan, measurement of c-reactive protein on treatment days, measurement of CBC indicators and biochemical factors such as urea and creatinine

Timepoint

Check of the patient's clinical condition and blood sampling of patients on days 1-14 in the hospital and also on the 28th day after the onset of the disease

Method of measurement

Measuring CBC indicators and biochemical factors using an autoanalyzer and examining heart function using EKG, Measurement of other factors using a thermometer and blood pressure monitor and patient bedside examinations.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:35 participants in the investigational treatment group will receive trifluoprazine at a dose of 5 mg twice daily for 14 days on admission in addition to standard treatment consisting of hydroxychloroquine. If necessary, according to the approved treatment protocol, kaletra and ribavirin would be added to the treatment

Category

Treatment - Drugs

2

Description

Control group:35 participants in control group, would receive standard treatment protocol consisting hydroxychloroquine and , if necessary, according to the approved treatment protocol, kaletra and ribavirin would be added to the treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital , Infectious Disease Clinic

Full name of responsible person

Dr Masood Ziaee

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Birjand University of Medical Sciences , Ghafari Street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tooba Kazemi

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Ghafari Street, Birjand, Southern Khorasan, Iran.

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Masood Ziaee

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Kazem Dastjerdi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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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

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

Birjand University of Medical Sciences

Full name of responsible person

Motahareh Mahi-Birjand

Position

Post-board Resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy