Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, trifluoprazine 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 trifluoprazine 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

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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 trifluoprazine 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 Oxigen 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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