Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Mar 2023

Evaluation of Trifluoperazine Effectiveness in Treatment Process, Survival rate and Cure rate of COVID-19 Patients

Protocol summary

Study aim
Evaluation of Trifluoperazine Effectiveness in Treatment of COVID-19 Patients

Design
Two arm parallel group randomized controlled trial including 70 patients with blinded major researcher and outcome assessment

Settings and conduct
This study will be conducted in April-May 2020, at Razi Hospital, Rasht, Guilan Province, Iran.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: All of the patients admitted to Razi hospital,Rasht, diagnosed for COVID-19 in April-March 2020,equal or older than 18 years, Fever (oral temperature more than 37.8) and at least one of the following criteria: Respiratory rate 24 and more per minute At rest SpO2 fewer than 94 PCR positive Pulmonary involvement in CT or chest X-ray Patients with following criteria will not included in the study: Lack of personal satisfaction, concomitant use of an antipsychotics, history of seizure disorders, Parkinson, Dementia, hepatic dysfunction, pheochromocytoma, sensitivity to phenothiazines, any major drug interaction with current medications, pregnancy and breast-feeding, previous COVID-19 treatment, bradycardia with fewer than 60/min, evidence of multi-organ failure, need to ventilatory support

Intervention groups
Intervention: Recommended standard care for COVID-19 patients + Trifluoperazine, 2 mg tablet PO (manufactured by Sobhandarou, Iran) q12hr for 21 days Control group: Recommended standard care alone for COVID-19 patients

Main outcome variables
Time to clinical improvements at least during 21 days from beginning of treatment: normalization of body temperature to 37.2 and lower, normalization of respiratory rate to 24 and fewer, Oxygen saturation of 94% and more Variable measurement: clinical evaluation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200329046892N1**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date
2020-05-02, 1399/02/13

Registrant information

Name
Nematollah Ahangar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3369 0099

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-05-27, 1399/03/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of Trifluoperazine Effectiveness in Treatment Process, Survival rate and Cure rate of COVID-19 Patients

Public title
Trifluoperazine Effectiveness in Treatment of Coronavirus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All of the patients admitted to Razi hospital of Rasht and diagnosed for COVID-19 in April-March 2020 18 years old and more Fever (oral temperature more than 37.8) At least one of the following criteria Respiratory rate 24 and more per minute At rest SPO2 fewer than 94 PCR positive Pulmonary involvement in CT or chest X-ray
Exclusion criteria:
Those who aren't willing to participate in the study based on personal satisfaction concomitant use of an anti-psychotic drug History of epileptic disorders Parkinson's Disease Dementia Symptomatic hepatic dysfunction Allergic reaction to Phenothiazines History of pheochromocytoma Any major drug-interaction between routine-taken drugs with trifluoperazine Pregnancy and breastfeeding Previous COVID-19 treatment Multi-organ failure evidences Need to mechanical ventilation on entrance to the study eGFR< 50 mL/min
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
70 COVID-19 patients divide to 2 groups each comprising 35 patients, case and control naming A and B, respectively. Randomized blocking will conduct as numbers 1-70 allocate consequently to research units. Then a table will draw including 6 rows named Block, each block having 4 segments filled with A and B. In next stage, the numbers will placed next to each other. The subjects would received A package if they had the numbers placed in A segment. About the subjects being opposite to B segments, B package would allocate to them. Concealment is done via sealed package.
Blinding (investigator's opinion)
Single blinded
Blinding description
Treatment group would be determined just after randomization. Subjects and physicians corresponding to patients' health would n't be blinded. Radiologists, main researchers, outcome assessor and statistician would be blinded to treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
School of Medicine, Guilan University Complex, 7th Km Tehran Road
City
Rasht
Province
Guilan
Postal code
4199613769
Approval date
2020-04-19, 1399/01/31
Ethics committee reference number
IR.GUMS.REC.1399.021

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
J00-J99
ICD-10 code description
بیماری های تنفسی

Primary outcomes

1

Description
Time to clinical improvment: normalization of body temperature to 37.2 and lower
Timepoint
Daily
Method of measurement
Clinical examination

2

Description
Time to clinical improvment: normalization of respiratory rate to 24 and fewer
Timepoint
Daily

Method of measurement
Clinical examination

3

Description
Time to clinical improvment: Oxygen saturation of 94% and more
Timepoint
Daily
Method of measurement
Palse oximeter

Secondary outcomes

1

Description
need to ventilator
Timepoint
Daily
Method of measurement
Clinical assessment

2

Description
Radiologic changes
Timepoint
21st day or anytime based on clinical team diagnosis
Method of measurement
Chest imaging

3

Description
serious adverse drug reactions
Timepoint
anytime
Method of measurement
clinical evaluation

4

Description
Morbidity
Timepoint
anytime
Method of measurement
clinical evaluation

Intervention groups

1

Description
Intervention group: Recommended standard care for COVID-19 patients + Trifluoperazine, 2 mg tablet PO (manufactured by Sobhandarou, Iran) q12hr for 21 days
Category
Treatment - Drugs

2

Description
Control group: Recommended standard care for COVID-19 patients
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Seyed Ali Alavi
Street address
Sardar Jangal Ave.
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4199613769
Phone
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aalavi_foumani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Naghipour
Street address
Shahid Siadati Ave.. Namju St.
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Postal code
4144666949
Phone
+98 13 3333 6394
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Nematollah Ahangar
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Pharmacology
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Person responsible for updating data

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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
Data about outcomes
When the data will become available and for how long
Summer 2020
To whom data/document is available
researchers
Under which criteria data/document could be used
requested by authenticated scientific centers and universities
From where data/document is obtainable
Dr. Nematollah Ahangar School of Medicine
What processes are involved for a request to access data/document
Official request signed by highest executive is

mandatory. Moreover, acceptable reasons should be noted.

Comments