

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

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)

Phone

+98 13 3369 0099

Email address

n.ahangar@gums.ac.ir

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 improvement: normalization of body temperature to 37.2 and lower

Timepoint

Daily

Method of measurement

Clinical examination

2

Description

Time to clinical improvement: normalization of respiratory rate to 24 and fewer

Timepoint

Daily

Method of measurement

Clinical examination

3**Description**

Time to clinical improvement: Oxygen saturation of 94% and more

Timepoint

Daily

Method of measurement

Pulse 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

+98 13 3354 1001

Email

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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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

Ph.D.

Other areas of specialty/work

Pharmacology

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Full name of responsible person

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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 usedrequested 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