

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 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.

**City**

Rasht

**Province**

Guilan

**Postal code**

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.

**City**

Rasht

**Province**

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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**

Ph.D.

**Other areas of specialty/work**

Pharmacology

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Km Tehran road**City**

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**Province**

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

Rasht University of Medical Sciences

**Full name of responsible person**

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

Rasht University of Medical Sciences

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Associate Professor

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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**