Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of Grapex on the alternations of clinical symptoms and laboratory finding on COVID19.

Protocol summary

Study aim
Evaluation of the effect of Grapex on the alternations of clinical symptoms and laboratory findings in patients with coronary hospitalization in Abadan hospitals.

Design
Clinical trial with control group, and parallel groups, double-blind, randomized, phase 3 on 80 patients

Settings and conduct
investigation of clinical symptoms and laboratory findings due to use of Grapex on covid-12 patients in abadan hospitals. Patients and researchers are blinded as double blind. Include treatment and control groups. Control group: The patients receive county protocol with placebo Treatment group: The patients receive county protocol with Grapex 200 mg, twice a day for 2 weeks. The desired outcomes are compared before treatment and at the discharge time.

Participants/Inclusion and exclusion criteria
COVID-19 patients that have positive PCR test COVID-19 patients that have positive by CT Scan for COVID-19. Exclusion criteria: Pregnant or breast feeding women, Patients under 18 years of age, Any life-threatening factor

Intervention groups
Control group: The patients receive county protocol with placebo Treatment group: The patients receive county protocol with Grapex 200 mg, twice a day for 2 weeks.

Main outcome variables
Time to clinical alternations defined as start of taking medication time to Discharge Time.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200921048783N1**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **prospective**
Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date
2020-12-06, 1399/09/16

Registrant information

Name
Hoda Mojiri-Forushani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5326 5361

Email address
dr.mojiri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-08, 1399/10/19

Expected recruitment end date
2021-04-08, 1400/01/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Grapex on the alternations of clinical symptoms and laboratory finding on COVID19.

Public title
Effect of GRAPEX in treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with covid19 by positive PCR test.

Patients diagnosed with covid19 by positive CT scan evaluation

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researchers are blinded as double blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Abadan school of Medical Sciences

Street address

Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

City

Abadan

Province

Khouzestan

Postal code

6319811154

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.ABADANUMS.REC.1399.098

Health conditions studied

1

Description of health condition studied

covid19

ICD-10 code

U07

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Time to clinical alternations defined as start of taking medication time to Discharge Time.

Timepoint

The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

Method of measurement

Medical record

Secondary outcomes

1

Description

Complete Blood Count

Timepoint

The beginning of the study and the time of discharge

Method of measurement

Blood sample

2

Description

C-reactive-protein

Timepoint

The beginning of the study and the time of discharge

Method of measurement

Blood sample

3

Description

SER

Timepoint

The beginning of the study and the time of discharge

Method of measurement

Blood sample

4

Description

creatinine

Timepoint

The beginning of the study and the time of discharge

Method of measurement

Blood sample

5

Description
Aspartate amino transferase
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

6

Description
Alanine amino transferase
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

7

Description
Prothrombin time
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

8

Description
Partial Thromboplastin time
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

9

Description
cough
Timepoint
The beginning of the study ,the seventh day, the fourteenth day
Method of measurement
Clinical observation and examination

10

Description
level of consciousness
Timepoint
The beginning of the study ,the seventh day, the fourteenth day
Method of measurement
Using the Glasgow Coma scale

11

Description
Arterial oxygen saturation
Timepoint
The beginning of the study ,the seventh day, the fourteenth day
Method of measurement
Blood sample

12

Description
Blood pressure
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Clinical examination

13

Description
Level of serum sodium
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

14

Description
Level of serum potassium
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

15

Description
BUN
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

16

Description
INR
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

17

Description
Mortality rate
Timepoint
Daily
Method of measurement
Blood sample

18

Description
Number of days of hospitalization
Timepoint
Daily
Method of measurement
Medical record

19

Description
Alkaline phosphatase
Timepoint
The beginning of the study and the time of discharge
Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group: Patients receiving standard country protocol drugs with Grapex 200 mg twice a day until the patient's clinical symptoms improve .
Category
Treatment - Drugs

2

Description
Control group: Patients receiving standard country protocol drugs with placebo twice a day until the patient's clinical symptoms improve .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Hoda Mojiri-Forushani
Street address
Ayatollah Taleghani Hospital; University Blvd; Nurse Square; Abadan city
City
Abadan
Province
Khouzestan
Postal code
6311911154
Phone
+98 61 5326 7800
Email
dr.mojiri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Sara Mobarak
Street address
Abadan School of Medical Sciences; Beginning of the 30 meters Ave; Zolfaghari street; Abadan city.
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Khouzestan
Postal code
631911154
Phone
+98 61 5338 4004
Email
s.mobarak@ abadanums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Abadan 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
Abadan University of Medical Sciences
Full name of responsible person
Hoda Mojiri-Forushani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.
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6313833177
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Email
dr.mojiri@yahoo.com

Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hoda Mojjiri-Forushani
Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Position
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dr.mojiri@yahoo.com

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
All data can be shared after the participants in the study are unrecognizable.
When the data will become available and for how long
The data access period after printing the article
To whom data/document is available
The data in this study will be available to researchers working at academic and scientific institutions, as well as the Food and Drug Administration.
Under which criteria data/document could be used
Any analysis can be done with the consent of the main researcher.
From where data/document is obtainable
dr.mojiri@yahoo.com
What processes are involved for a request to access data/document
The researcher or pharmaceutical company can send their request to the academic email after sending the documents to confirm their original identity.The project manager will then provide the requested information to the researcher or pharmaceutical company after ensuring the accuracy of the submitted documents after a period of one week.
Comments