

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 May 2022

Effective of Elman tablet on illness severity and length of hospital stay in the patients with COVID-19 infection

Protocol summary

Study aim

This study aimed to determine the effects of Elman tablet on illness severity and length of hospital stay patients with Covid-19 infection.

Design

This study is a three-group clinical trial, parallel and without blinding, and phase three of the clinical trial. Patients are divided into control, intervention and placebo groups based on a random number table. Pilot study is performed to determine the sample size.

Settings and conduct

The study population is patients referring to Corona ward of Imam Khomeini Hospital in Esfarayen. After conducting a pilot study and determining the sample size, patients are divided into three groups. Elman Tablet (60 mg) are given orally three times a day for up to six days. In the placebo group, the placebo is prescribed three times a day with the same appearance as the main drug. The control group also receives routine treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients diagnosed with COVID-19 disease based on PCR test and their level of consciousness should be 15. Exclusion criteria: Pregnancy and lactation, Connect the patient to the ventilator, Low blood pressure at the beginning of the study, Has a history of gastrointestinal bleeding or active bleeding in the body, Patients with immunodeficiency (under chemotherapy and patients with autoimmune diseases)

Intervention groups

Intervention group: In addition to routine treatment, Elman Tablet (60 mg) is given orally three times a day for up to six days. In the placebo group: The placebo is given three times a day with a similar appearance to the main drug containing maltodextrose. Control group: Patients receive routine treatment

Main outcome variables

Primary outcome: severity of the illness based on changes in CBC, CRP test levels, need for supplemental

oxygen, SPO2 level, physical symptoms (fever, cough, sore throat and myalgia) Secondary outcome: length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200609047707N1**

Registration date: **2020-06-24, 1399/04/04**

Registration timing: **prospective**

Last update: **2020-06-24, 1399/04/04**

Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Essa Towhidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3724 1702

Email address

issatohidi201648@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-09, 1399/04/19

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effective of Elman tablet on illness severity and length of hospital stay in the patients with COVID-19 infection

Public title
Effective of Elman tablet on COVID-19 infection severity

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with COVID-19 disease based on PCR test The level of consciousness should be 15
Exclusion criteria:
Pregnancy and lactation Connect the patient to the ventilator Low blood pressure at the beginning of the study (below 80/12) Has a history of gastrointestinal bleeding or active bleeding in the body Patients with immunodeficiency (under chemotherapy, organ transplantation and bone marrow transplantation, and patients with autoimmune diseases)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. Random units are each of patients infected with covid-19 that admitted to the emergency department. Also, The randomization tool is a random number table. The researcher select one of the numbers in the random numbers table and moves to the right and down. Record the numbers and assign them to different study groups whose numbers are already specified.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfarayen faculty of medical sciences
Street address
Esfarayen faculty of medical sciences, Imam Reza street, Esfarayen, North Khorasan
City
Esfarayen
Province
North Khorasan
Postal code
9661876981
Approval date
2020-06-07, 1399/03/18
Ethics committee reference number
IR.ESFARAYENUMS.REC.1399.003

Health conditions studied

1

Description of health condition studied
Patients infected with Covid-19
ICD-10 code
U07.1
ICD-10 code description
Covid-19

Primary outcomes

1

Description
Illness severity
Timepoint
Every 12 hours for six day
Method of measurement
Using the checklist

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
It is controlled daily
Method of measurement
Calculate the number of days hospitalized within the corona ward

Intervention groups

1

Description
First Intervention group (Elman Tablet): The tablet has an effective drug combination of L-cysteine, C3H7NO2S chemical formula and chemical structure of HS-CH2-CH

(NH₂)-COOH with L stereochemistry and a molar mass of 121.16 grams per mole and soluble in water. Each Elman tablet contains 60 mg of L-cysteine (Pharmaceutical active ingredient). Each patient takes this pill three times every 8 hours. It is recommended to take this medicine at least two hours apart from the prescription of the routine medications for six days. Manufacturing Company is Simorgh Attar Neishabour Pharmaceutical . It is prescribed along with routine drugs for treatment of covid-19.

Category

Treatment - Drugs

2**Description**

Second Intervention group (Placebo): It contains a combination of malodextrin, an oligo or polysaccharide with the formula C₆nH₁₀n + 2 O₅n + 1, and is obtained from starch hydrolysis in a simple process. The powder is white and soluble in water. The placebo is given with a very similar appearance to the original medicine and is given orally every 8 hours for six days. Drugs associated with the treatment of Qovid-19 disease are prescribed according to the routine.

Category

Placebo

3**Description**

Control group: Drugs associated with the treatment of Covid-19 disease are prescribed according to the routine (hydroxychloroquine 200 mg and Kaletra).

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital of Esfarāyen

Full name of responsible person

Essa Tohidi

Street address

Esfarayen faculty of medical sciences, Imam Reza street, Esfarayen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

96618-76981

Phone

+98 58 3722 6005

Email

Issatohidi201648@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfarayen University of Medical Sciences

Full name of responsible person

Eshagh Ildarabadi

Street address

Esfarayen faculty of medical sciences, Imam Reza street, Esfarayen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

96618-76981

Phone

+98 58 3722 6005

Email

Info@esfrums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfarayen 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**

Esfarayen University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Member of Esfarayen faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Esfarayen faculty of medical sciences, Imam Reza street, Esfarayen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

9661777944

Phone

0098 5831550000- 602

Email

S.j.hoseini2016@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfarayen University of Medical Sciences

Full name of responsible person

Essa Tohidi

Position

Deputy for treatment in Esfarayen faculty of medical sciences

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Esfarayen faculty of medical sciences, imam Reza Street, Esfarayen town, North Khorasan, Iran

City

Esfarayen

Province

North Khorasan

Postal code

96617-77944

Phone

+98 58 3722 9050

Email

Issatohidi201648@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfarayen University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Member of Esfarayen faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Esfarayen faculty of medical sciences, Imam Reza street, Esfarayen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

96617-77944

Phone

0098 58 3155 0000-602

Email

S.j.hoseini2016@gmail.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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Document will be registered "Pajouhan" system after completion of the study . Also, participants general information and the effectiveness of interventions will be recorded in the article.

When the data will become available and for how long

Accessibility after publish of article

To whom data/document is available

People interested in medicine scope

Under which criteria data/document could be used

People looking for ways to covid-19 recovery who can access the data.

From where data/document is obtainable

Esfarāyen faculty of medical sciences, imama Reza Street, Esfarāyen, North Khorasan

What processes are involved for a request to access data/document

They can access to data through below email as soon as possible s.j.hoseini2016@gmail.com

Comments