Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2026

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