

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

(NH<sub>2</sub>)-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 C<sub>6</sub>nH<sub>10</sub>n + 2 O<sub>5</sub>n + 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

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

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

Esfarayen University of Medical Sciences

**Full name of responsible person**

Eshagh Ildarabadi

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**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**

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## 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

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## Person responsible for updating data

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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

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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**

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**