

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Evaluation of the effect of Lemon Balm/ Star anice in treatment of COVID-19 patients as well as their prophylactic effects in close contacts with COVID-19 patients

#### Protocol summary

##### Study aim

Evaluation of the effect of Lemon Balm or Star anice in prophylaxis in close contacts and treatment of COVID-19 patients in Bojnurd

##### Design

Shuffle block randomization Triple blinding Capsules and their packaging are similar in terms of their appearance. Only A, B, C have been labelled on them

##### Settings and conduct

Patients enrolling the clinics in Bojnurd

##### Participants/Inclusion and exclusion criteria

inclusion criteria Prophylactic study: Those who live with a Covid-19 patient in a single house. Have not had Covid-19 (or its symptoms) so far. Maximum 7 days have passed since start of Covid-19 symptoms Treatment study: Covid-19 patients, Maximum 7 days have passed since start of Covid-19 symptoms. Have not taken anti-virus drugs in the last 14 days exclusion criteria pregnant/ breast feeding women Underlying diseases hepsensivity to herbal drug used in this study or their derivatives use of antiviral drugs in the last 2 weeks use of immune suppressor medicine use of serotonin inhibitor or othee sedative medicines

##### Intervention groups

Lemon Balm capsule Star Anice capsule Placebo

##### Main outcome variables

Prophylactic study: clinical/lab confirmation of the disease hospitalization due to COVID-19 death due to COVID-19 Treatment study: Changes in state of patient hospitalization due to COVID-19 death due to COVID-19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150902023864N2**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-15, 1399/12/25**

Update count: **1**

##### Registration date

2021-02-08, 1399/11/20

##### Registrant information

###### Name

Amir Amani

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 218899111824

###### Email address

aamani@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of Lemon Balm/ Star anice in treatment of COVID-19 patients as well as their prophylactic effects in close contacts with COVID-19

patients

### Public title

Evaluation of the effect of Lemon Balm/ Star anise in treatment of COVID-19 patients as well as their prophylactic effects in close contacts with COVID-19 patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Prophylactic study: Those who live with a Covid-19 patient in a single house. Prophylactic study: Have not had Covid-19 (or its symptoms) so far. Prophylactic study: Maximum 7 days have passed since start of Covid-19 symptoms Treatment study: Covid-19 patients Treatment study: Maximum 7 days have passed since start of Covid-19 symptoms. Treatment study: Have not taken anti-virus drugs in the last 14 days

#### Exclusion criteria:

pregnant/ breast feeding women Underlying diseases hepsensitivity to herbal drug used in this study or their derivatives use of antiviral drugs in the last 2 weeks use of immune suppressor medicine use of serotonin inhibitor or othee sedative medicines

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Data analyser

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Shuffle block randomization To conceal the data, the medicines will have same packaging and will have a single code. So that the prescriber and the researcher will not know about the medicine. Sampling will be based on shuffle block randomization. For instance the block 1 has been given below.. In sample 1 of the block one we have 1, 3, 1, group a, PP1. This shows that in block 1, having block size of 3, we give group 1 to the first sample with code PP1 Group A: treatment A, Group B: treatment B, Group C: Treatment C Block sizes: 3 block identifier, block size, sequence within block, treatment code • 1, 3, 1, group a, PP1 • 1, 3, 2, group b, CT2 • 1, 3, 3, group c, WV6

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

Capsules and their packaging are similar in terms of their appearance. Only A, B, C have been labelled on them

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

##### Street address

Shahriar

##### City

Bojnurd

##### Province

North Khorasan

##### Postal code

9417694735

#### Approval date

2020-01-13, 1398/10/23

#### Ethics committee reference number

IR.NKUMS.REC.1399.093

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Prophylactic study: clinical/lab confirmation of the disease

#### Timepoint

weekly

#### Method of measurement

examination- PCR test

### 2

#### Description

Prophylactic study: hospitalization due to Covid-19

#### Timepoint

weekly

#### Method of measurement

Hospital report

### 3

#### **Description**

Treatment study: general state of patient

#### **Timepoint**

weekly

#### **Method of measurement**

examination

### 4

#### **Description**

Treatment study: hospitalization due to Covid-19

#### **Timepoint**

weekly

#### **Method of measurement**

Hospital report

### 5

#### **Description**

Treatment study: death due to Covid-19

#### **Timepoint**

weekly

#### **Method of measurement**

Hospital report

### 6

#### **Description**

Prophylactic study: death due to Covid-19

#### **Timepoint**

weekly

#### **Method of measurement**

hospital report

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Lemon Balm capsule (Manobrain, Rahman Daroo)- Twice per day

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: Star Anice capsule (Manoflo- Rahman daroo)- Twice per day

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: Placebo (starch capsules with same appearance to the intervention groups)- Twice per day

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Ali special clinic

##### **Full name of responsible person**

Dr Ahmad Hashemi

##### **Street address**

Shahriar

##### **City**

Bojnurd

##### **Province**

North Khorasan

##### **Postal code**

9417694735

##### **Phone**

+98 58 3221 0940

##### **Email**

amani76@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza clinic

##### **Full name of responsible person**

دکتر محمد رضا تقوی

##### **Street address**

Safa

##### **City**

بجنورد

##### **Province**

North Khorasan

##### **Postal code**

9417694735

##### **Phone**

+98 58 3229 7157

##### **Email**

amani76@gmail.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

16-h Imam Ali health center

##### **Full name of responsible person**

Amir Amani

##### **Street address**

No 86. Shahriar Street

##### **City**

Bojnurd

##### **Province**

North Khorasan

##### **Postal code**

947694735

##### **Phone**

+98 58 3223 7444

##### **Email**

amani76@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Rahman Gostaran

**Full name of responsible person**

Peyman Akbarian

**Street address**

Near Vahdat gas station, Qazvin Karaj Road, Qazvin

**City**

قزوین

**Province**

Qazvin

**Postal code**

3491872868

**Phone**

+98 21 2205 8772

**Email**

info@rahmangostaran.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rahman Gostaran

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Amir Amani

**Position**

academic member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

No 90, Shahriar street

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

amani76@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Amir Amani

**Position**

academic member

**Latest degree**

Ph.D.

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Medical Pharmacy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

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**Email**

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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**  
Not applicable  
**Title and more details about the data/document**

All data potentially may be shared  
**When the data will become available and for how long**  
Nearly in a year  
**To whom data/document is available**  
All people  
**Under which criteria data/document could be used**  
there is no condition  
**From where data/document is obtainable**  
they can email the PI  
**What processes are involved for a request to access data/document**  
We do our best to deliver the data in a month  
**Comments**