

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 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

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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Amir Amani

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Email

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Person responsible for updating data

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

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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