Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 heprsensitivity 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

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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 anice 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 heprsensitivity 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 Khorsan 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
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North Khorasan
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9417694735
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amani76@gmail.com

2

Recruitment center
Name of recruitment center
Imam Reza clinic
Full name of responsible person
دکتر محمدرضا تقوی
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Safa
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بجنورد
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+98 58 3229 7157
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amani76@gmail.com

3

Recruitment center
Name of recruitment center
16-h Emam Ali health center
Full name of responsible person
Amir Amani
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No 86. Shahriar Street
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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
acadmic member
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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 peaple

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