

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effects of green tea consumption compared with black tea on the severity of symptoms, some serum marker, and fatigue, depression and anxiety scores in COVID-19 patients

Protocol summary

Study aim

Determination of the effects of green tea consumption compared to black tea on the severity of symptoms, some serum marker and fatigue, depression and anxiety scores in outpatients with COVID-19

Design

Clinical trial with control group, with parallel groups, no blinding, randomized, phase 2 on 84 patients. Random permutation block method will be used to allocate consumption to the subjects. The website <http://www.randomization.com> will also be used for randomization.

Settings and conduct

A total of 84 patients with COVID-19 virus confirmed by PCR test referred to a private office or clinic of an infectious disease specialist will be included in the study. Patients in two groups of 42 will be treated with green tea as a drink (3 glasses per day) or black tea (3 glasses per day as a control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19; Twice positive PCR test; Age over 20 years; Provide written consent to enter the study; Not participating in other clinical trials; no use of other types of herbal teas. Exclusion criteria: Pregnancy or breastfeeding; Obesity (body mass index more than 30 kg per square meter) History of heart attack or stroke; history of coronary bypass graft or coronary angioplasty, hospitalization history with heart failure; Underlying diseases including chronic hepatitis, cirrhosis and cholestatic liver disease and severe renal failure; Chronic obstructive pulmonary disease or severe pneumonia; Active gastrointestinal ulcers.

Intervention groups

Intervention group: Patients with covid 19 will consume three cups of green tea daily for four weeks from Heshmat Fooman tea factory. Control group: Patients with covid 19 will consume three cups of black tea daily

for four weeks from Heshmat Fooman tea factory.

Main outcome variables

The severity of symptoms; some serum marker; fatigue, depression, and anxiety scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038626N8**

Registration date: **2021-05-09, 1400/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-09, 1400/02/19**

Update count: **0**

Registration date

2021-05-09, 1400/02/19

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

zahmadnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of green tea consumption compared with black tea on the severity of symptoms, some serum marker, and fatigue, depression and anxiety scores in COVID-19 patients

Public title
Effects of green tea consumption on fatigue, depression and anxiety scores in COVID-19 patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
patients with COVID-19 Twice positive PCR test Age over 20 years Provide written consent to enter the study Not participating in other clinical trials no use of other types of herbal teas
Exclusion criteria:
Pregnancy or breastfeeding Obesity(body mass index more than30 kg per square meter) History of heart attack or stroke, history of coronary bypass graft or coronary angioplasty, hospitalization history with heart failure Underlying diseases including chronic hepatitis, cirrhosis and cholestatic liver disease and severe renal failure Chronic obstructive pulmonary disease or severe pneumonia Active gastrointestinal ulcers

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized permutation block method will be used for allocating consumption of black or green tea to the subjects of the study, and considering quadruple blocks, 21 blocks will be produced for 84 patients. The website <http://www.randomization.com> will also be utilized for randomization. Moreover, in order to conceal the random allocation procedure, encrypted envelopes with random sequence will be used. Each subject's envelope will be opened after approving the person's eligibility for entering the study and Therefore, group A are the patients who receive green tea and group B are the patients that receive black tea.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.GUMS.REC.1399.670

Health conditions studied

1

Description of health condition studied

Coronavirus disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Severity of the viral infection clinical symptoms

Timepoint

At the beginning of the study and 7, 14 and 21 days after tea consumption

Method of measurement

The severity of clinical signs of viral infection will be detected through a respiratory rate more than 24 or a heart rate greater than 125 or the patient requires mechanical ventilation or saturation of peripheral oxygen less than 94% and also based on the patient's laboratory results including D- dimer more than 1000; creatinine phosphokinase twice the normal amount; positive troponin; progressive lymphopenia; ferritin more than 300.

2

Description

Complete blood cell count and differential count

Timepoint

At the beginning of the study and one month later

Method of measurement

Cell counter devices

3

Description

C-reactive protein

Timepoint

At the beginning of the study and one month later

Method of measurement

ELISA device

4

Description

Lactate dehydrogenase

Timepoint

At the beginning of the study and one month later

Method of measurement

Biochemical autoanalyzer

5

Description

Creatinine phosphokinase

Timepoint

At the beginning of the study and one month later

Method of measurement

Biochemical autoanalyzer

6

Description

Troponin

Timepoint

At the beginning of the study and one month later

Method of measurement

ELISA device

7

Description

D-dimer

Timepoint

At the beginning of the study and one month later

Method of measurement

ELISA device

8

Description

Ferritin

Timepoint

At the beginning of the study and one month later

Method of measurement

ELISA device

Secondary outcomes

1

Description

Depression score based on Patients Health Questionnaire-9

Timepoint

At the beginning of the study and one month later

Method of measurement

Patients Health Questionnaire-9

2

Description

Scale of fatigue based on Chalder Fatigue Scale (CFQ-11)

Timepoint

At the beginning of the study and one month later

Method of measurement

Chalder Fatigue Scale (CFQ-11) Questionnaire

3

Description

Scale of anxiety based on State-Trait Anxiety Inventory (STAI) Questionnaire

Timepoint

At the beginning of the study and one month later

Method of measurement

State-Trait Anxiety Inventory (STAI) Questionnaire

Intervention groups

1

Description

Intervention group: Patients with Covid 19 will be consumed daily with three cups of green tea equivalent to 12 grams of green tea per day from Heshmat Fooman tea factory for four weeks.

Category

Treatment - Other

2

Description

Control group: Patients with Covid 19 will be consumed daily with three cups of black tea equivalent to 12 grams of black tea per day from Heshmat Fooman tea factory for four weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Marjan Mahdavi Roshan

Street address

Razi Educational and Medical Center, Sardar Jangal St.

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3355 0028

Email

razi.hospital@yahoo.com

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

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 5821

Email

naghi@gums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

80

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

2**Sponsor****Name of organization / entity**

Heshmat Tea Factory

Full name of responsible person

Abbas Mohebkhah

Street address

Heshmat tea Factory; km 6 of Qaleh Rudkhan road; Foman

City

Foman

Province

Guilan

Postal code

4358115371

Phone

+98 13 3471 4257

Email

heshmattea@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Heshmat Tea Factory

Proportion provided by this source

20

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**

Rasht University of Medical Sciences

Full name of responsible person

Zahra Ahmadnia

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Fax**Email**

zahmadnia@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Marjan Mahdavi Roshan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Dr. Heshmat Hospital; Bayani St; Mosala Square;
Rasht.

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Email

Marjanmahdavi60@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Zahra Ahmadnia

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Dr. Heshmat Hospital; Bayani St; Mosala Square;
Rasht.

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Fax**Email**

gums.icrc@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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Request to receive unidentifiable personal data or other documents

From where data/document is obtainable

Marjan Mahdavi Roshan

What processes are involved for a request to access data/document

By email to Dr.Marjan Mahdavi Roshan

Comments