

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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**

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**Phone**

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**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;  
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**Province**

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**Postal code**

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+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**

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**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**

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**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**