

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of powdered green tea enriched with epigallocatechin gallate (EGCG) on some clinical, electrophysiological, biochemical, inflammatory and antioxidant parameters in patients with coronary artery disease, a randomized, triple blind clinical trial

#### Protocol summary

##### Study aim

The effect of powdered green tea enriched with EGCG on some clinical, electrophysiological, biochemical, inflammatory and antioxidant parameters in patients with coronary artery disease

##### Design

Clinical trial with community-based control and pragmatism-based control group, with parallel groups, triple blind, randomized

##### Settings and conduct

Patients who referred to the angiographic unit of Ali-Ibn Abitaleb hospital of Rafsanjan will randomly divided into two groups. In each group, patients will take capsules for 3 months. Electrophysiological, clinical, biochemical, anti-inflammatory and antioxidant variables will be evaluated at baseline and 3 months after the intervention.

##### Participants/Inclusion and exclusion criteria

Coronary artery stenosis based on Gensini's criteria, willingness to participate in the study and age 40 and above are inclusion criteria. Allergy to green tea or components, the use of any antioxidant supplement, daily green tea intake before and during the study, follow a special diet, participate in another study, alcohol consumption, Candidate for coronary artery bypass graft surgery and pregnancy, diseases such as Alzheimer's disease, schizophrenia, kidney, urinary tract and osteoporosis, unstable angina and arrhythmia are exclusion criteria.

##### Intervention groups

In intervention group patients will use 500 mg capsules of green tea powder enriched with 88 mg of polyphenol total and 11.2 mg of EGCG twice a day for 3 months. In control group, cellulose is used as a placebo for capsules and will be used in the same way as the intervention group. Two capsules Manufacturing by Giah Essence

Phytopharm Company.

##### Main outcome variables

re-admission, systolic and diastolic blood pressure, quality of life, serum Triglycerides , Low and high density lipoprotein , Cholesterol, blood sugar, total antioxidant capacity and Interleukin 10 serum, anthropocentric parameters, heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181203041835N1**

Registration date: **2019-02-19, 1397/11/30**

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

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

##### Registration date

2019-02-19, 1397/11/30

##### Registrant information

##### Name

Elham Hassanshahi raviz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3432 4336

##### Email address

e.hassanshahi94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2018-12-22, 1397/10/01

**Expected recruitment end date**

2020-08-22, 1399/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of powdered green tea enriched with epigallocatechin gallate (EGCG) on some clinical, electrophysiological, biochemical, inflammatory and antioxidant parameters in patients with coronary artery disease, a randomized, triple blind clinical trial

**Public title**

The effect of powdered green tea in patients with coronary artery disease

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

coronary artery stenosis above 50% at least in one of the major coronary arteries and clinical stability, based on the Gensini criteria the willingness to participate in the study Age 40 and older

**Exclusion criteria:**

include allergy to green tea or components and green tea products the use of any antioxidant supplement daily intake of green tea before and during the study follow a special diet participate in another study alcohol intake candidate for surgery Coronary artery bypass graft (CABG) pregnancy lactation perceptual disorders unstable angina arrhythmia Diseases such as kidney and urinary tract and osteoporosis

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as age and sex. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Drug and placebo were delivered as drugs 1 and 2, and the researcher will blind to placebo or drug of capsules. The patient also will not know that he is in the drug group or placebo. The analyst will not know the groups and will perform the analysis as group 1 and 2.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

**Street address**

Central Administration of Rafsanjan University of Medical Sciences, Imam Ali Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2018-10-14, 1397/07/22

**Ethics committee reference number**

IR.RUMS.REC.1397.120

**Health conditions studied****1****Description of health condition studied**

Coronary Artery Disease (CAD)

**ICD-10 code**

I25.9

**ICD-10 code description**

Chronic ischaemic heart disease, unspecified

**Primary outcomes****1****Description**

re-admission

**Timepoint**

Before intervention and 3 months after study

**Method of measurement**

Number of patients re-admission

## 2

### **Description**

Systolic blood pressure

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Digital barometer

## 3

### **Description**

diastolic blood pressure

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Digital barometer

## **Secondary outcomes**

## 1

### **Description**

Quality of Life

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

SF36 quality of life questionnaire

## 2

### **Description**

triglycerides

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Autoanalysis machine

## 3

### **Description**

low density lipoprotein

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Autoanalysis machine

## 4

### **Description**

high density lipoprotein

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Autoanalysis machine

## 5

### **Description**

cholesterol

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Autoanalysis machine

## 6

### **Description**

blood sugar

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Autoanalysis machine

## 7

### **Description**

Total capacity antioxidant

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

German Zellbio chromogen kit and Spectrophotometer

## 8

### **Description**

Anti-Inflammatory Cytokine Level IL-10

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

German-made Zellbio kits and Enzyme-linked immunosorbent assay (ELISA)

## 9

### **Description**

Weight

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Digital Scale

## 10

### **Description**

Body mass index

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Using the formula: Weight (kg) per square meter height

## 11

### **Description**

Waist circumference

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

Strip meter

## 12

### **Description**

wrist circumference

### **Timepoint**

Before intervention and 3 months after study

### **Method of measurement**

**13****Description**

Abdominal circumference

**Timepoint**

Before intervention and 3 months after study

**Method of measurement**

Strip meter

**14****Description**

Heart rate

**Timepoint**

Before intervention and 3 months after study

**Method of measurement**

Digital monitor device

**Intervention groups****1****Description**

Control group: The group that consumes a 500 mg capsule containing cellulose .Daily two capsules for 3 months.This capsule is prepared by the Essential Oil Pharmaceutical Company.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: The group that consumes a 500 mg capsule containing EGCG-rich green tea powder.Daily two capsules for 3 months.This capsule is prepared by the Essential Oil Pharmaceutical Company.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ali Ibn Abitaleb Hospital

**Full name of responsible person**

Dr. Ali Esmaeili Nadimi

**Street address**

Ali Ibn Abitaleb Hospital, Mofateh Blvd

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Rafsanjan

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

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Shamsizadeh

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

Yes

**Title of funding source**

Rafsanjan University of Medical Sciences

**Proportion provided by this source**

100

**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

**Person responsible for general inquiries****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Elham Hassanshahi Raviz

**Position**

Master's degree in medical physiology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiology

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Medical School, Revolution Square, Rafsanjan

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Dr. Ali Shamsizadeh  
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Ph.D. in Physiology  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Elham Hassanshahi Raviz  
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Master's degree in medical physiology  
**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### Study Protocol

Undecided - It is not yet known if there will be 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