Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of powdered green tea enriched with epigallocatchin 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)

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+98 34 3432 4336

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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 epigallocatchin 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 committe 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

Strip meter

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
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Ali Ibn Abitaleb Hospital, Mofateh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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7717933777
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vcrt@rums.ac.ir
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
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Person responsible for updating data

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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