

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, biochemical, inflammatory, antioxidant and cognitive parameters in stroke patients; a double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Determination of the effect of EGCG-rich green tea powder on some clinical, biochemical, inflammatory, anti-oxidant and cognitive parameters in patients with ischemic stroke in a triple-blind, placebo-controlled clinical trial.

Design

This study was randomized controlled trial triple blind with parallel control group.

Settings and conduct

Rafsanjan Aliebe Abitaleb Hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: 1- Patients referred to hospital in the first day of the stroke. 2- Patients with 30 to 80 years old. 3. Patients have completed the consent form. 4. Patients with an ischemic stroke. 5. Patients with an ischemic stroke of supratentorial. - Exclusion criteria : 1- Patients with hemorrhagic stroke. 2. Patients with severe stroke. (NIHSS> 25) 3 Patients with an ischemic stroke of lacunar and inferatentorial type. 4. Patients taked tPA. 5. Patients who have secondary stroke due to autoimmune disorders such as lupus and autoimmune hemolytic anemia and other inflammatory diseases. 6- pregnant patients .

Intervention groups

Intervention group: patients will take EGCG-enriched green tea powder twice a day (120 milligrams) as well as routine drugs associated with ischemic disease. Control group: patients will take placebo tablets (cellulose vegetables, magnesium stearates, silica or maltodextrine) and routine drugs associated with ischemic disease.

Main outcome variables

Clinical Index (NIHSS, MRS and Quality of Life); BDNF Factor; Biochemical Index (LDL, HDL, Total Cholesterol, Triglycerides, Blood Glucose and CBC); Inflammatory and

angiogenesis Index (TNF- α , IL-1 β , IL -10, CRP, ESR, CXCL12, CCL2, CXCL9 and CXCL10); antioxidant index (Total Antioxidant Capacity and ROS); cognitive function (MMSE test, Montreal test, Aden Burke cognitive test and Lotte cognitive test)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040927N1**

Registration date: **2018-10-04, 1397/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-04, 1397/07/12**

Update count: **0**

Registration date

2018-10-04, 1397/07/12

Registrant information

Name

Mahdieh Azin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3131 5072

Email address

m.azin@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-21, 1398/01/01

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, biochemical, inflammatory, antioxidant and cognitive parameters in stroke patients; a double-blind, placebo-controlled clinical trial

Public title

Effect of Green Tea on Stroke

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients have referred in the 1st day of the stroke
Patients was 30 and 80 years old. Patients who have completed the Consent form. Patients with an ischemic stroke. Patients with supratentorial ischemic stroke

Exclusion criteria:

Patients with hemorrhagic stroke Patients with severe stroke (NIHSS> 25). Patients with lacunar and inferatentorial type of ischemic stroke . Patients received tPA. Patients who have secondary stroke due to autoimmune disorders such as lupus and autoimmune hemolytic anemia and other inflammatory diseases. stroke patients have Pregnant.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of intervention and sham based on the random numbers table and then will enter the study process. So, for the first time, for the use of a random number table, according to the total number of 80 stroke patients to be included in the study, each person is given a two-digit code. Then, for selecting the sample individuals from the table, by closing the eye and putting the finger on the table and moving in the direction of the column to the top. The two left-handed numbers in each column block

are selected, the number must be less than 40. This shows 40 people in the intervention group. The same method will be done to determine the subjects in the placebo group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Green tea capsules and placebo tablets are completely similar in similar box have given to the original researcher by the pharmaceutical company Essential Oil. On the box, only numbers 1 and 2 are recorded, and participants, university researchers, hospital staff, data collection officer, data analyzer are not aware of which box of green tea and which placebo is. The box with 1 label is given to one group and box with 2 label is given to another group.

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

Rafsanjan University of Medical Sciences, School of Medicine, Pistachio Street, Gulf Blvd., Rafsanjan,

City

rafsanjan

Province

Kerman

Postal code

7718175911

Approval date

2018-01-21, 1396/11/01

Ethics committee reference number

IR.RUMS.REC.1396.201

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

stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

National Institutes of Health Stroke Scale

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

National Institutes of Health Stroke Scale

2

Description

Measurement index of stroke disability

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Modified Rankin Scale

3

Description

Life Quality score

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Based on the life quality questionnaire

4

Description

Brain-Derived Neurotrophic Factor

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

ELISA method

5

Description

Lipid profile

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Auto analyzer

6

Description

Interleukin-10

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

ELISA method

7

Description

Tumor necrosis factor alpha

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

ELISA method

8

Description

Mini-Mental State Examination score

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Mini-Mental State Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To receive 60 mg capsules containing green tea powder with 40% effective epigallocatechin gallate twice daily

Category

Treatment - Other

2

Description

Control group: To receive capsules containing vegetable cellulose, magnesium stearate, silica or maltodextrine as a placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

aliebn Abitaleb Hospital

Full name of responsible person

Dr. Ali Mozafari

Street address

Aliebn Abitaleb Hospital, , Mofatheh Boulevard, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

0

Phone

+98 34 3428 0000

Email

aliebn@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Shamsy zadeh

Street address

Central Organization, Imam Ali Blvd., Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

alishamsy@gmail.com

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

Mahdieh Azin

Position

Assistant Professor of Neuroscience

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Faculty of Medicine, Rafsanjan University of Medical Sciences, Pistachio St., Persian Gulf Blvd., Rafsanjan, Iran

City

Rafsanjan

Province

Kerman

Postal code

0

Phone

+98 34 3131 5079

Fax

Email

mahdieh.azin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Mahdieh Azin

Position

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Faculty of Medicine, Rafsanjan University of Medical Sciences, Pistachio St., Persian Gulf Blvd., Rafsanjan, Iran

City

Rafsanjan

Province

Kerman

Postal code

0

Phone

+98 34 3131 5079

Fax

Email

mahdieh.azin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Mahdieh Azin

Position

Assistant Professor of Neuroscience

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Fax

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mahdieh.azin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form

No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable