

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of green tea enriched with EGCG on some inflammatory, antioxidant and cognitive factors in methadone maintenance patients; Triple-blind clinical trial

Protocol summary

Study aim

Determination of the effect of green tea enriched with EGCG on some inflammatory, antioxidant and cognitive factors in methadone maintenance patients; Triple-blind clinical trial

Design

این مطالعه از نوع کارآزمایی بالینی تصادفی شده سه سو کور با گروه موازی کنترل میباشد

Settings and conduct

The methadone maintenance patients with inclusion criteria will be selected from the Mehregan Center in Rafsanjan. participants, university researchers, hospital staff, data collection officer, data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with methadone maintenance are 20 and 70 years old. Patients who have completed the Consent form. People who have not an underlying inflammatory or infectious disease. Exclusion criteria: Patients who are allergic to green tea. Patients are taking antioxidant supplements daily and regularly. People who have a special diet like vegetarian. People who consumed green tea daily before the study

Intervention groups

Intervention group: To receive 60 mg capsules containing green tea enriched with 40% effective epigallocatechin gallate twice daily for 3 months Control group: To receive capsules containing vegetable cellulose, magnesium stearate, silica or maltodextrine as a placebo twice daily for 3 months.

Main outcome variables

Study variables include inflammatory indicators (C-reactive protein (CRP), Tumor necrosis factor (TNF- α)), antioxidant indicators (Total antioxidant capacity (TAC)), Superoxide dismutase enzyme (Superoxide dismutase (SOD), Catalase (CAT), Glutathione peroxidase (GPx) and Reactive oxygen species (ROS), Addiction Severity Index, Depression and Anxiety degrees.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040927N5**

Registration date: **2021-04-18, 1400/01/29**

Registration timing: **prospective**

Last update: **2021-04-18, 1400/01/29**

Update count: **0**

Registration date

2021-04-18, 1400/01/29

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

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Before taking drug and after 3 months of taking drug

Method of measurement

ELISA method

3

Description

Total antioxidant capacity

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Spectrophotometric method

4

Description

Superoxide dismutase

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Spectrophotometric method

5

Description

Catalase

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Spectrophotometric method

6

Description

Glutathione peroxidase

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Spectrophotometric method

7

Description

Reactive oxygen species

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Spectrophotometric method

8

Description

Addiction Severity Index

Timepoint

Before taking drug and after 3 months of taking drug

Method of measurement

Addiction Severity Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To receive 60 mg capsules containing green tea enriched with 40% effective epigallocatechin gallate twice daily for 3 months

Category

Treatment - Other

2

Description

Control group: To receive capsules containing vegetable cellulose, magnesium stearate, silica or maltodextrine as a placebo twice daily for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan Addiction Treatment Center

Full name of responsible person

Mahdieh Azin

Street address

Mehregan Addiction Treatment Center, Unit 1, First Floor, Imamat Building, Zaytoun St., Rafsanjan

City

Rafsanjan

Province

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0

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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

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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

Mahdieh Azin

Position

Assistant Professor of Neuroscience

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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