# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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

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**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

**Scientific title**

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

**Public title**

Effect of Green Tea on Methadone Maintenance Patients

**Purpose**

Supportive

**Inclusion/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

**Age**

From **20 years** old to **70 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample size of the present study will be 40 people, which is considered to be 45 people due to the possibility of falling during the study. In order to assign individuals to the two groups, statistical software R version 4.0.3 and simple randomization method were used. Using the command code below, 45 people were randomly divided into two groups a and b. sample (c ("a", "b"), 45, replace = TRUE, prob = c (.5, .5)) By executing this command, the following result was obtained. "b" "b" "a" "b" "a" "a" "b" "a" "a" "a" "b" "b" "a" "a" "a" "b" "a "" b "" a "" b "" b "" a "" b "" b "" a "" a "" a "" b "" b "" a "" b "" b "" b "" a "" a "" b "" b "" a "" a "" b "" b " The first person to enter the study should be in group b, the second person in group b, the third person in group a, the fourth person in group b, and so on. All 45 people will be in the groups. Intervention a and 23 people will be in intervention group b.

**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**

2021-01-18, 1399/10/29

**Ethics committee reference number**

IR.RUMS.REC.1399.236

## Health conditions studied

### 1

**Description of health condition studied**

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

C-reactive protein

**Timepoint**

Before taking drug and after 3 months of taking drug

**Method of measurement**

ELISA method

### 2

**Description**

Tumor necrosis factor -α

**Timepoint**

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
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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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**Phone**
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**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**
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Assistant Professor of Neuroscience
**Latest degree**
Ph.D.
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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

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

**Data Dictionary**