

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of green tea consumption on markers of oxidative stress in Alzheimer's patients

Protocol summary

Summary

In this study, the effects of green tea consumption on markers of oxidative stress in Alzheimer's disease, was investigated. In this study, we enrolled thirty patients with severe probable AD. The diagnostic criteria was National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA) criteria, with the Mini-Mental State Examination was lower than 24 (MMSE) and age was higher than 67. Inflammatory and infectious diseases, vitamins and folic acid supplementation were the exclusion criteria. Patients consumed four green tea pills per day for two months (2g per day in 2 divided doses. Plasma total antioxidant capacity levels, 8-hydroxy-2'-deoxyguanosine levels, malondialdehyde levels, carbonyl content levels were measured before and after dietary intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402233684N5**
Registration date: **2015-08-15, 1394/05/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-15, 1394/05/24

Registrant information

Name

Soleiman Mahjoub

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-04-19, 1393/01/30

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of green tea consumption on markers of oxidative stress in Alzheimer's patients

Public title

The effect of green tea in the treatment of Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Alzheimer's disease
Inclusion
Exclusion: Taking vitamin and antioxidant supplements; drugs interfering; inflammatory diseases; acute and chronic infectious disease; thalassemia; diabetes; hepatitis

Age

From **67 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Gange afrose st, Babol

City

Babol

Postal code

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

3609

Health conditions studied

1

Description of health condition studied

Alzheimer

ICD-10 code

G30.8

ICD-10 code description

Other Alzheimer disease

Primary outcomes

1

Description

Malondialdehyde

Timepoint

Before intervention, 2 months after the end of intervention

Method of measurement

TBARS Method (spectrophotometry)

2

Description

Total antioxidant capacity

Timepoint

Before intervention, 2 months after the end of intervention

Method of measurement

FRAP Method

3

Description

8-OH-2-deoxy-Guanosine

Timepoint

Before intervention, 2 months after the end of intervention

Method of measurement

ELISA

4

Description

Carbonyl

Timepoint

Before intervention, 2 months after the end of intervention

Method of measurement

Levin Method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention :Green tea,2 mg orally tablets, 2 times a day for 2 months

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehravaran Shomal nursing home

Full name of responsible person

Dr. Mehdi Moghadasi

Street address

Keshavarz Blvd, Sari, Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences Research Deputy

Full name of responsible person

Dr. Ali Bijani

Street address

Babol University of Medical Sciences, Ganj afrooz st,
Babol

City

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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

Babol University of Medical Sciences Research Deputy

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

MSc in Clinical Biochemistry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty