

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Effect of oral administration of green tea on DPPH free radical scavenging , level of zinc, iron and copper in the serum of patients with Alzheimer's disease

Protocol summary

Summary

The aim of this study is to investigate the serum levels of trace elements zinc, copper, iron and 2,2-Diphenyl-picrylhydrazyl (DPPH •) radical scavenging power in Alzheimer's patients before and after green tea consumption. Alzheimer's disease (AD), is the most prevalent degenerative disorder of the brain, among elderly individuals. Many studies indicate that zinc, copper and iron participate in redox reactions, by producing the hydroxyl radicals. It has been suggested that green tea is a strong metals chelator that can remove reactive oxygen species in the hippocampus of the brain. This prospective interventional study will conduct on 30 patients with AD. The diagnostic criteria is 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 ≤ 10 (MMSE) and age ≥ 65 . Inflammatory and infectious diseases, vitamins and folic acid supplementation are the exclusion criteria. Patients will swallow four green tea tablets per day for two months (2g per day in 2 divided doses). DPPH radical level and levels of trace elements will determine before and after dietary intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612063684N8**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

Soleiman Mahjoub

Name of organization / entity

Babol University of Medical Sciences

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research of Babol University of Medical Sciences

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2017-10-12, 1396/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral administration of green tea on DPPH free radical scavenging , level of zinc, iron and copper in the serum of patients with Alzheimer's disease

Public title

The effect of taking green tea on patients with Alzheimer's

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Mini-mental state examination score between 0-10; rejection of other causes of dementia by performing MRI, CT scans and laboratory tests (TSH, T3, T4, CBC / DIFF, BUN / CR, FBS, LFT and ESR) . exclusion criteria: green tea allergy; inflammatory and infectious diseases such as hepatitis, anemia, and diabetes; treated with antioxidant agents such as vitamin E, C, A and folic.

Age

From **65 years** old to **139 years** old

Gender

Both

Phase

2-3

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)

Single 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

University of Medical Sciences, Ganjafrooz Street,
Babol, Mazandaran ,Iran

City

Babol

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2013-09-06, 1392/06/15

Ethics committee reference number

3609

Health conditions studied

1

Description of health condition studied

Alzheimer

ICD-10 code

G30.1

ICD-10 code description

Alzheimer disease with late onset

Primary outcomes

1

Description

DPPH free radical level

Timepoint

Before the intervention and two months after the end of the intervention

Method of measurement

according to percent by using the Brand-Williams method

2

Description

trace elements zinc

Timepoint

Before the intervention and two months after the end of the intervention

Method of measurement

In micrograms per deciliter using colorimetric method

3

Description

trace elements iron

Timepoint

Before the intervention and two months after the end of the intervention

Method of measurement

In micrograms per deciliter using colorimetric method

4

Description

trace elements copper

Timepoint

Before the intervention and two months after the end of the intervention

Method of measurement

In micrograms per deciliter using colorimetric method

Secondary outcomes

empty

Intervention groups

1

Description

Patients will take 1 gr oral green tea tablet twice a day (2 gr per day in 2 divided doses) for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehravarar

Full name of responsible person

Dr. Mehdi Moghadasi

Street address

Mehravarar-Shomal nursing home, Kayasar Road

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Soleiman Mahjoub

Street address

University of Medical Sciences, Ganjafrooz Street,
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City

Babol

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

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

Babol University of Medical Sciences

Full name of responsible person

Soleiman Mahjoub

Position

Ph.D. 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