

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of dietary supplementation of the elderly suffering from mild cognitive impairment (MCI) with antioxidant vitamins C and E in Esfahan, Iran.

Protocol summary

Summary

This interventional research will be carried out in Iran and include about 222 elderly. The object of this study is to determine whether use of supplemental antioxidants (vitamins C and E) will be associated with Mild Cognitive Impairment in a representative sample of elderly. The criteria for inclusion is aged between 60-75 years old in both sexes with educational level of fifth grade and upper. The exclusion criteria are severely sick and disabled in terms of having neurological problems, history taking in neuroleptic medicine, severe cardiovascular disease, anemia, liver and kidney disorders and mal-absorption, smokers, alcohol and opium addiction. Participants with eligibility criteria mentioned above will be recruited from retirement clubs and urban health centers. In order to identify the subjects with MCI, they will be interviewed by two standard questionnaires including Mini Mental State Examination (MMSE) and short IQCODE (Informant Questionnaire on Cognitive Decline). Sample was selected using stratified random sampling techniques. Stratification will be done on the basis of age groups (60-65, 65-70, 70-75,) and gender. Subjects with MCI divided to intervention and control group and informed consent will be obtained after explaining the plan to each subject. Intervention group will receive 400 mg vitamin C and 300 mg vitamin E, one time daily for one year and control group will take one time daily placebo manufactured exactly similar to the color, shape and size. Information on background characteristics, lifestyle factors and 3-Day Diet Recall will be collected. The effects of Antioxidant Supplements on study subjects will be assessed at baseline, after six months and post-intervention by measuring cognitive performance and also redox status with appropriate laboratory test including: Total Antioxidant Capacity (TAC), Malondialdehyde assay, 8-hydroxydeoxyguanosine (8-

OHdG) and Glutathione assay. The comparison includes intervention and control groups, men and women and also different age groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104186217N1**

Registration date: **2011-05-15, 1390/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-15, 1390/02/25

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences (Iran) Vienna University (Austria)

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2011-05-01, 1390/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dietary supplementation of the elderly suffering from mild cognitive impairment (MCI) with antioxidant vitamins C and E in Esfahan, Iran.

Public title

Effect of vitaminC and E on MCI (mild cognitive impairment)among elderly people in Esfahan , iran

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: a. Aged between 60-75 years old in both sexes. b. Educational level of fifth grade and upper. Exclusion Criteria: a. Dementia, Depression, Epilepsy, Mental retardation, History of temporary loss of consciousness more than 2 hours due to head trauma, Memory problems that interfered with daily functioning , History of brain surgery and any significant neurological disease . b. History taking in medicine such as: neuroleptic drugs, benzodiazepine, anti-Depression, anti-epilepsy and opioids 7 days before interview by MMSE. c. Severe CVD (cardiovascular disease), anemia , liver and kidney disorders and mal-absorption. d. Alcohol and opium addiction, smokers .

AgeFrom **60 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **222****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences & Ministry Of Health in Iran

Street address

sixth floor, central building of Tehran University of Medical Sciences,Ghods str., Tehran, Iran

City

Tehran

Postal code**Approval date**

2011-01-10, 1389/10/20

Ethics committee reference number

۱-۳۶/پ۸۹ ک

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

Mild Cognitive Impairment (MCI)

ICD-10 code

F06.7

ICD-10 code description

Mild cognitive disorder

Primary outcomes**1****Description**

Cognitive Performance

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

The Informant Questionnaire on cognitive decline in the elderly(IQCODE) Questionnaires

2**Description**

Cognitive Performance

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

The mini-mental state examination(MMSE)

Secondary outcomes**1****Description**

Measurment of Malondialdehyde assay for oxidative stress status of subjects

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

laboratory Methods

2

Description

Measurment of Serum total antioxidant capacity for oxidative stress status of subjects

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

laboratory Methods

3

Description

Measurments of 8-hydroxy-2'-deoxyguanosine for oxidative stress status of subjects

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

laboratory Methods

4

Description

Measurment of Glutathion for oxidative stress of subjects

Timepoint

Before intervention, after intervention and 6 months after intervention

Method of measurement

laboratory Methods

Intervention groups

1

Description

Intervention group will receive daily antioxidants as follows: 400 mg vitamin C or L-ascorbic acid and 300 IU or mg vitamin E (Alfa- Tocopheryle Acetate), one time daily for one year.

Category

Treatment - Drugs

2

Description

Control group will take one time daily placebo manufactured exactly similar to the color, shape and size of Vitamin C and E tablets.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Retirement Club & Urban Health Center in Esfahan- Iran

Full name of responsible person

Mr. Moteei & Dr. Pejman Aghdak

Street address

Next to Bosorgmehr Bridge- Bosorgmehr Str. Kanoon Bazneshastegan Keshvari-Esfahan -Iran

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Younesian

Street address

Sixth floor, Central Building of Tehran University of Medical Sciences, Ghods Str., Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vienna University

Full name of responsible person

Prof. Ibrahim Elmadfa

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University of Vienna. Dr. Karl-Lueger-Ring1-1010 Vienna- Austria

City

Vienna

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vienna University

Proportion provided by this source

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

Amirmansour Alavi Naeini

Position

Faculty Member (instructor)

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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