Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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

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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 .
Age
From **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
ک ۸۹پ/۳۶-۱

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) Questionaires

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
City
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
Street address
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

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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