Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Effectiveness of selenium in epileptic patient’s cognitive function compared with control group

Protocol summary

Study aim
Determining of effectiveness of selenium on cognitive function in epileptic patients.

Design
Two arm parallel group randomized trial with blinded postoperative care and outcome assessment.randomized allocation rule method was used.

Settings and conduct
Two blind randomized clinicsl trial will be done with 70patients who refered to the vali-e-asr zanjan hospital, then patients randomly divided inti two group of experimental and placebo group. all the patients, referral physician, stratification will not know about the type of drug.patients in experimental group will be given tab selenium 200mcg, and who are in placebo group, the tab placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patient with idiopathic generelized epilepsy between 20-60 Satisfaction for patcipation in the study. Patiens who past at least 1year from the onset of the disease. Patient who have not had changed their drug regime from one month to the end of intervention. Exclusion criteria: patient who had seizure within one week ago. Moca score more than 20 Presence of major psychiatric disease:depression, mood disorder, psychosis, mental retardation

Intervention groups
Experimental group (35patients)and placebo group(35patients), who in addition to main treatment of their disease receive selenium and placebo respectively for 4months.

Main outcome variables
Improvement in cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101209005352N3**
Registration date: **2018-10-29, 1397/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-03, 1397/11/14**
Update count: **1**

Registration date
2018-10-29, 1397/08/07

Registrant information

Name
Mehdi Maghbooli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3347 2576

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-06, 1397/05/15

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of selenium in epileptic patient’s cognitive function compared with control group

Public title
Selenium in epilepsy.

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Adult pateints between 20_60 year’s old suffering from idiopathic generelized epilepsy. Satisfaction for participation in the study. Patients who passed at least one year from onset of the epilepsy. Patients who haven't been changed their antiepileptic drugs from one month befot to the end of intervention.
Exclusion criteria:
Patients who had seizure during one week ago. Moca score higher than 29. Pateints who suffer from major psychiatric disorders such as mood disorder, psychosis, mental retardation &...
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is based on random allocation rule which has different way to do .in this study 35 is used for first group & the same number is used for rhe second group. after mixing rhe cards one card is extracted & allocation is recorded then backed to the others. this process continue until reaching to the randomized succession according to the sample size. non transparent cards is used for allocation concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
For All patients who participate in the study are explained that they will be divide into two groups. one group will receive drug and the other wil receive placebo but any patient know about which group she/he is placed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of zanjan university of medical siences.
Street address
Vali-e-asr squ, vali-e-asr hospital,zanjan,iran
City
Zanjan
Province
Zanjan
Postal code
451577978
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
ZUMS.REC.1396.267

Health conditions studied

1

Description of health condition studied
Epilepsy
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
The epileptic patient’s cognitive status based on moca test.
Timepoint
Moca test at the start of study,2month &4month later.
Method of measurement
Moca test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: epileptic patients,tab selenium 200mcg ,one tabletin at breakfast for 4months ,21centry(purapakhsh)company included purified selenium; as an antioxidant.
Category
Treatment - Drugs

2

Description
Control group: epileptic patients,tab selenium placebo 200mcg,one tab at breakfast ,for 4months,purapakhsh company.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-e-asr hospital
Full name of responsible person
Rosa davallou
Street address
Vali-e-ast squ,vali-e-asr hospital
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Dr_rosadavallou@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr.alireza shoghli
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Vali-e-asr squ , vali-e-asr hospital,zanjan
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Mehdi maghbooli
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total data will be shared after removal of the pateint’s names.
When the data will become available and for how long
Starting6 months after publication the results.
To whom data/document is available
The data will only be available for academic institutions.
Under which criteria data/document could be used
Different analysis will only be available for academic resarchers.
From where data/document is obtainable
Dr mehdi maghbooli / m.maghbooli@zums..ac.ir .vali-e-asr square. Vali-e-asr hospital ,zanjan ,iran. phone number: 00982433770801postal code :4515777978
What processes are involved for a request to access data/document
Email the requst for documents /within one week
Comments