**Clinical Trial Protocol**

**Iranian Registry of Clinical Trials**

18 Jul 2022

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

**Protocol summary**

**Study aim**
Determining the 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 clinical trial will be done with 70 patients who referred to the Vali-e-Asr Zanjan hospital, then patients randomly divided into two groups of experimental and placebo group. All the patients, referral physician, stratification will not know about the type of drug. Patients in the experimental group will be given 200mcg of selenium, and those in the placebo group will receive the placebo.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:
- Patient with idiopathic generalized epilepsy between 20-60 years old.
- Satisfaction for participation in the study.
- Patients who have not had changes in their drug regime from one month to the end of the intervention.

Exclusion criteria:
- Patients who had seizure within one week ago.
- Moca score more than 20.
- Presence of major psychiatric diseases: depression, mood disorder, psychosis, mental retardation.

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

**Main outcome variables**
Improvement in cognitive function.

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**General information**

**Reason for update**

**Acronym**
IRCT

**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

**Registrant information**

**Name**
Mehdi Maghbooli

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 24 3347 2576

**Email address**
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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 patients between 20-60 year's old suffering from idiopathic generalized 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 before to the end of intervention.

Exclusion criteria:
Patients who had seizure during one week ago. MoCA score higher than 29. Patients 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 the second group. After mixing the 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 will 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 sciences.

Street address
Vali-e-asr sq, 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, 2-month & 4-month later.

Method of measurement
MoCA test

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: epileptic patients, tab selenium 200mcg, one tablet at breakfast for 4 months, 21st century (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 4 months, 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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4515777978
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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
Street address
Vali-e-asr squ , vali-e-asr hospital,zanjan
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Email
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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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4515777978
Phone
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Email
M.maghbooli@zums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mehdi maghbooli
Position
Associate professor
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 patient's names.

When the data will become available and for how long
Starting 6 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 researchers.

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: +98 982433770801. Postal code: 4515777978

What processes are involved for a request to access data/document
Email the request for documents /within one week

Comments