Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effectiveness of a herbal product (Fenosha) as add-on therapy in uncontrolled epileptic patients: a randomized, double blinded, placebo controlled study

Protocol summary

Study aim
Investigating the effect of a herbal medicine on controlling the frequency of seizures

Design
A randomized, parallel group, double blinde, placebo controlled trial

Settings and conduct
This study was conducted at Neurology Clinic of Imam Hussein Hospital. Patients are referred to the clinical pharmacist by neurologist after they evaluated by a neurologist if they are qualified to enter into the study. After complete information about the study is provided to the patients, drug/placebo will be delivered to the patient if agreed. Laboratory tests will taken included CBC, Plt, AST, ALT, Alp, BUN, (Cr, Pt, Ptt, INR, drug levels (if applicable) At the start of the study, and every month, up to three months. The patient's assessment will be done monthly, and the frequency of seizure and possible side effects will be documented.

Participants/Inclusion and exclusion criteria
Patients older than 15 years of age who have had at least 3 seizures in the last 3 months are included in the study. Patients whose seizures have no apparent symptoms or are susceptible to psychogenic epilepsy are excluded.

Intervention groups
Patients are divided into two groups. The first group is taking 500 mg (of one component) of herbal medicine three times a day. The second group receives capsules of the same appearance but containing placebo. Both groups take the delivered medications for 3 months.

Main outcome variables
Frequency of seizure in patients; percentage of people who have had at least 50% reduction in seizure frequency; adverse effects reported by the patient

General information

Reason for update
Adding data related to innovation

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N17**
Registration date: **2019-03-05, 1397/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-10, 1398/12/20**
Update count: **1**

Registration date
2019-03-05, 1397/12/14

Registrant information
Name
Mohammad Sistanizad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8820 0087
Email address
sistanizadm@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effectiveness of a herbal product (Fenosha) as add-on therapy in uncontrolled epileptic patients: a randomized, double blinded, placebo controlled study

Public title
Fenosha study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 15 years old Take one or two anti-epileptic drugs at least 2 months before entering the study At least 1 seizure per month for 3 consecutive months Patient agrees to enter the study
Exclusion criteria:
Simple partial epilepsy without motor symptoms Known and progressive neurological disorder Status or cluster epilepsy within 3 months before entering the study History of psychogenic epilepsy in the last 2 years Uncontrolled illness or drug use associated with impaired Lab data (liver enzyme at least twice upper limit of normal or Creatinine clearance less than 50 ml / min) Non compliance Pregnancy or breastfeeding
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization was done by block randomization method using a randomization table made with statistical software with four blocks and individual randomization unit. To hide this table, there is only one copy of this table without specifying the study groups that are maintained by the study host in the center.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, due to the use of capsules of similar weight and appearance and similar drug canisters, drugs and placebo can not be distinguished from each other. Medications are given with three-character codes, including two letters and one number. A neurologist who introduces the patient to the study does not know what drug will be deliver to the patient. Due to the fact that it is not included in the randomization list of the study groups, the drug deliverer is blind to the delivered drug and, given the very similar appearance of the drug and the placebo, there is no way to determine the type of drug delivery for the patient and the investigator. The assessor is a self-delivering scholar who does not know the patient group. Only one person outside the study has a list of groups for each group, which only provides the original researcher if there is a report of serious side effect or the completion of study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
Province
Tehran
Postal code
1991953381
Approval date
2018-10-08, 1397/07/16
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.122

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
Seizure frequency
Timepoint
30, 60, 90 days
Method of measurement
Patient and families's remarks

Secondary outcomes

1

Description
Safety and adverse drug reactions
Timepoint
30, 60, 90 days
Method of measurement
Patient's remarks

Intervention groups

1

Description
Intervention group: Fenosha group (herbal product) It contains two gums called dorema ammoniacum and ferula persica, mixed in capsules with a ratio of 70 to 30 to a final weight of 500 milligrams. Capsules are packed in cans in a packet of 90. This oral capsule is given three times a day for 3 months to patients and provided by Afkar-e Talaee Pharmaceutical and Industrial institute by registration ID of 43624. This product has invention certificate with below specification: owner: Reza Mazloom-Farsibaf, inventors: Reza Mazloom-Farsibaf with national ID of 0930792998 and email address of: rezamfb1978@gmail.com and Arshia Mazloom-Farsibaf with national ID of 0926044796 and email address of: rezamf1978@gmail.com, invention name: herbal product for treatment of seizure and epilepsy and international category: A61B
Category
Treatment - Drugs

2

Description
Control group: placebo Includes capsules with a completely similar appearance and the same weight filled with lactose powder in a package of the same appearance and number, given three times a day for 3 months. Placebo capsules are also provided by Afkar-e Talaee Pharmaceutical and Industrial institute by registration ID of 43624
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic, Imam hussein hospital
Full name of responsible person
Omid Hesami
Street address
Imam hussein hospital, Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Email
sistanizadm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zarghi, Afshin
Street address
Shahid Beheshti medical University, aarabi St., Yemen St., chamran Hwy, Velenjak St.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9781
Email
Mpajouhesh@sbmu.ac.ir
Web page address
http://retech.sbmu.ac.ir/index.jsp?siteid=24
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associate professor
Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0087
Fax
+98 21 8820 0087
Email
sistanizadm@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0087
Fax
+98 21 8820 0087
Email
sistanizadm@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0087
Fax
+98 21 8820 0087
Email
sistanizadm@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Individual data will be shared: Demographic information, seizure frequency of each month, baseline seizure information, concomitant drugs and concomitant illnesses, reported infections.
When the data will become available and for how long
Staring 2 months after completion of sampling
To whom data/document is available
The information will be accessible to all categories by reviewing the applicant's eligibility.
Under which criteria data/document could be used
The sending person may include patients, legislators, researchers, university professors and students.
From where data/document is obtainable
Applicants must send their application along with the reason for the need for the study data to the principle investigator's email address.
What processes are involved for a request to access data/document
The request is evaluated within 2 weeks by the principal investigator and will be sent to the person or institution requested
Comments