Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

comparing the efficiency of agomelatine & sertraline in the depression & anxiety of patients suffering from psychogenic non-epileptic seizure (PNES)

Protocol summary

Study aim
Determining the effectiveness of agomelatine and sertraline in anxiety and/or depression and reducing the number of attacks in patients with PNES.

Design
Clinical trial without a control group, with parallel groups, double-blind, randomized, phase 2 on 34 patients. The website www.Randomization.com was used for randomization (online randomization). For this purpose, a simple randomization model was used.

Settings and conduct
After receiving the necessary permits to conduct the clinical trial, the study population will be selected from among the outpatients referred to the neurology clinic of Imam Hossein Hospital in Tehran.Patients with psychogenic non-epileptic seizures are diagnosed by a neurologist. Then, patients will complete the Hamilton questionnaire related to depression and anxiety. Then 34 patients will be randomized into two groups of 17 and each group will be treated with one of two drugs: agomelatine or sertraline. Further, for follow-up, the patients will be visited by a psychiatrist for one month, two months, and three months, and the Hamilton anxiety and depression questionnaire will be completed by them again, and the incidence of seizure attacks will be recorded. Patients and clinical caregivers will be blinded to the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Confirmation of PNES diagnosis by neurologist and psychiatrist 2. Not suffering from a mental disability and pregnancy 3. Age 18-65 years 4. Patient satisfaction exclusion criteria: 1. Patient's lack of consent to continue participating in the study 2. Confirmation of neurological disorder or other major disorders in addition to anxiety and depression during study 3. Not coming for a follow-up visit.

Intervention groups
Two intervention groups, 1: agomelatine (25-50 mg) or 2: sertraline (50-200 mg)

Main outcome variables
level of anxiety; level of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230626058586N3**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date
2024-02-19, 1402/11/30

Registrant information

Name
Nasim Sohrabifar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 938 229 6766

Email address
nasimsohrabifar@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-19, 1402/11/30

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the efficiency of agomelatine & sertraline in the depression & anxiety of patients suffering from psychogenic non-epileptic seizure (PNES)

Public title

Investigating the effect of agomelatine and sertraline on anxiety and depression

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of PNES diagnosis by neurologist and psychiatrist Not suffering from mental disability and pregnancy Age range between 18-65 years Patient satisfaction

Exclusion criteria:

Patient's lack of consent to continue participating in the study Confirmation of neurological disorder or other major disorders in addition to anxiety and depression during study Not coming for a follow-up visit.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

The website www.Randomization.com was used for randomization (online randomization). For this purpose, a simple randomization model was used. The randomization unit was individual and on this website, after specifying the number of intervention groups, which were three groups, and the required number in each of these groups, the website provided us with a random table of repetitions that represented the patient number. To hide the random allocation, central randomization was used. In this method, a random sequence is placed in the possession of an individual or a specific center, and sampling is done in one or more centers at the same time. Based on the order in which the participants entered the study, the researcher contacted the relevant center and asked about the random assignment of the participants to a special group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was double-blind and the patients and evaluators were unaware of the type of treatment. Also, the study data analyst only had the codes of the treatment groups (1, 2) and they were not able to distinguish the treatment groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Ethics Committee of Shahid Beheshti University of Medical Sciences, Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Velenjak st., Tehran.

City

Tehran

Province

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Postal code

1995825466

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.SBMU.MSP.REC.1401.391

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description
depression
Timepoint
before the intervention and one month, two months and three months after the intervention
Method of measurement
Hamilton questionnaire

2

Description
anxiety
Timepoint
before the intervention and one month, two months and three months after the intervention
Method of measurement
Hamilton questionnaire

Secondary outcomes

1

Description
Seizure attacks
Timepoint
before the intervention and one month, two months and three months after the intervention
Method of measurement
EEG

Intervention groups

1

Description
Intervention group: Agomelatine (25-50mg)
Category
Treatment - Drugs

2

Description
Intervention group: Sertraline (50-200 mg)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hossein hospital
Full name of responsible person
Roya Vaziri Harami
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Shahid madani street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roya Vaziri Harami
Street address
Shahid beheshti University of medical sciences Research Vice-Chancellor, Shahid Beheshti University of Medical Sciences, Arabi St., Daneshjoo Blvd., Volenjak St., Tehran.
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199852468
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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
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
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Position
associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available