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Use of a supplement called Memovigor-2 in tinnitus (a condition where a person hears a ringing or buzzing sound in their ears)

Submission date
20/03/2023

Recruitment status
No longer recruiting

Registration date
05/04/2023

Overall study status
Completed

Last Edited
20/02/2024

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tinnitus is a common condition where people hear sounds like ringing or whistling in their ears, even when there is no external noise present. It affects 15-20% of people, especially older adults. Most people have a mild form of tinnitus in quiet rooms, but it can be a problem if it's bothersome or affects hearing. It's usually associated with hearing loss, but it can happen to anyone. We don't know exactly what causes tinnitus, so it's hard to treat. A new drug called Memovigor2, made from natural ingredients, has been suggested as a treatment for recent-onset tinnitus. This type of tinnitus may be easier to treat because the brain is more adaptable. The aim of this study is to see if Memovigor2 can help treat tinnitus.

Who can participate?
Adults aged 18-70 years who suffer from recent-onset tinnitus.

What does the study involve?
Participants are asked to join this study when they come to our Audiology & Neurotology Department suffering from tinnitus that began during the last 12 months. Participants are randomly allocated to one of two groups. Those in the first group are given Memovigor-2 tablets, one daily, for 3 months. Those in the second group are given dummy tablets, also 1 tablet daily for 3 months. Participants of both groups complete questionnaires and objective audiological tests at the beginning and after 3 months of treatment. The study lasts until testing 80 patients of each group. The study is randomized double-blind, because participants are randomly allocated to one of the two groups, and they don’t know if they are given the drug or the dummy. Also, the examiner does not know to which group belongs each patient.

What are the possible benefits and risks of participating?
By taking part in this study there are no risks of physical injury or harm. The only known adverse reaction of the drug is a small effect on blood coagulation, which can present as bruises, or bleeding that does not stop easily with pressure. However, patients with blood coagulation disorders or using anticoagulants are excluded from the study. For the participants taking the drug, the benefit is a possible improvement of their tinnitus. Participants in the second group, if

the drug is proven useful, may gain by taking the drug after the end of the study. Also, many patients with recent-onset tinnitus may benefit from the results of this study.

Where is the study run from?
Audiology & Neurotology Department, Tzaneio General Hospital, Piraeus, Greece

When is the study starting and how long is it expected to run for?
December 2019 to September 2023

Who is funding the study?
The study is self-funded. However, the pharmaceutical company Bionat has provided the drug and the dummies.

Who is the main contact?
Dimitrios Balatsouras, dbalats@hotmail.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
14549-18/11/2019

Study information

Scientific Title
Memovigor-2 improves tinnitus in patients with recent onset disease: A randomized placebo-controlled study

Study objectives
To assess improvement of tinnitus using Memovigor-2 in patients with tinnitus of recent onset

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2019, Institutional Review Board of Tzaneio General Hospital of Piraeus (1 Afentouli, Piraeus, 18536, Greece; +30 2132081000; epistimonico.symvulio@tzaneio.gov.gr), ref: 14549/05-12-2019

Study design
Single-centre randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Tinnitus

Interventions
Patients participating in the research group (50%) are given 1 tablet 900 mg of Memovigor 2 (Bionat, Athens, Greece) daily for 3 months. Similar use of placebo is used in the remaining 50%, the control group. A sealed envelope with either drug or placebo is provided to the subjects of the study for the randomisation process.

Intervention Type
Supplement

Primary outcome measure
Tinnitus change is measured using Tinnitus Handicap Inventory questionnaire (THI) at baseline and 3 months

Secondary outcome measures
Current secondary outcome measures as of 04/07/2023:
1. Tinnitus severity is measured using Mini Tinnitus Questionnaire at baseline and 3 months
2. Evaluation of perceptional quality of tinnitus using specific measures of tinnitus perception (tinnitus loudness matching, tinnitus pitch matching, tinnitus minimum masking level, residual inhibition of tinnitus) at baseline and 3 months
3. Evaluation of hearing is measured using audiometry at baseline and 3 months
4. Perception of tinnitus change due to intervention measured using the Patient's Global Impression of Change (PGIC) at baseline and 3 months

Previous secondary outcome measures:
1. Tinnitus severity is measured using Mini Tinnitus Questionnaire at baseline and 3 months
2. Objective tinnitus evaluation is measured using objective tinnitus measurement tests (tinnitus loudness matching, tinnitus pitch matching, tinnitus minimum masking level, residual inhibition of tinnitus) at baseline and 3 months
3. Evaluation of hearing is measured using audiometry at baseline and 3 months.

Overall study start date
04/11/2019

Completion date
06/06/2023

Eligibility

Key inclusion criteria
1. Age 18 - 70 years
2. Suffering from tinnitus
3. Recent onset disease ≤12 months

Participant type(s)
Patient

Age group
Mixed

Lower age limit
17 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
80 per group (80 patients and 80 controls)

Total final enrolment
204

Key exclusion criteria
1. Patients with otosclerosis
2. Chronic otitis media
3. Hypo- or hyperthyroidism
4. Diabetes mellitus
5. Uncontrolled hypertension
6. Hypercholesterolemia
7. Coagulation disorders
8. Use of anticoagulants

Date of first enrolment
09/12/2019

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Greece

Study participating centre
Tzaneio General Hospital
Audiology & Neurotology Department
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Sponsor information

Organisation
Tzaneio General Hospital of Piraeus

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Sponsor type
Hospital/treatment centre

Website
https//www:tzaneio.gov.gr

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 20/02/2024:
The study was published in the journal of Frontiers in Pharmacology.

Previous publication and dissemination plan:
Planned publication in a PubMed-indexed peer-reviewed journal

Intention to publish date
24/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Dimitrios Balatsouras, dbalats@hotmail.com, participant level raw data, after publication for 5 years. The data will be anonymous and will be shared by E-mail to members of the Biomedical Community for scientific analysis. The data will be anonymous and no patient consent is required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/07/2023	No	No
Results article		24/01/2024	09/02/2024	Yes	No