ISRCTN39221710 https://doi.org/10.1186/ISRCTN39221710

Intratympanic dexamethasone plus melatonin versus melatonin in the treatment of acute idiopathic tinnitus

Submission date
26/11/2013

Recruitment status
No longer recruiting

Registration date
16/12/2013

Overall study status
Completed

Last Edited
16/12/2013

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Intratympanic drug delivery (a surgical technique of delivering medication into the middle ear) results in a higher drug concentration and very low side effects. Intratympanic dexamethasone has been used for treating a wide range of inner ear diseases and oral melatonin works well in relieving idiopathic tinnitus (ringing in the ears).

The study aims to assess whether intratympanic dexamethasone in association with oral melatonin is better than oral melatonin alone in the treatment of acute idiopathic tinnitus.

Who can participate ?
Adult male and female patients suffering acute tinnitus with no apparent cause for it.

What does the study involve ?
Patients will be randomly allocated to one of two treatment groups. One group of patients with acute idiopathic tinnitus will be treated with oral melatonin alone and another group will receive oral melatonin and intratympanic dexamethasone. At the end of the study we shall compare the relief of tinnitus in each group.

What are the possible benefits and risks of participation ?
Participants in the intratympanic dexamethasone plus melatonin group may experience a faster relief of tinnitus. The side effects include complications of intratympanic drug delivery, mainly acute otitis media (ear infection), transitory vertigo (dizziness), persistent eardrum perforations and hearing loss.

Where is the study run from?
The study is conducted at Spitalul Clinic CF Cluj Napoca, Romania.

When is the study starting and how long is it expected to run for ?
The study will start in December 2013 and will run until March 2014.

Who is funding the study ?
The study is funded by the researcher.

Who is the main contact ?
Dr Chirtes Felician

Contact information

Type(s)
Scientific

Contact name
Dr Felician Dorin Chirtes

Contact details
st Henri Barbusse nr 3-5
bloc Doina, ap 12
Cluj napoca
Romania
400616

Additional identifiers

Protocol serial number
864/20.09.2013

Study information

Scientific Title
Intratympanic dexamethasone plus melatonin versus melatonin in the treatment of acute idiopathic tinnitus a randomized clinical trial

Study objectives
We hypothesize that the association of intratympanic dexamethasone and oral melatonin will result in faster relief of tinnitus during the treatment of acute idiopathic tinnitus compared to oral melatonin alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Iuliu Haţieganu University of Medicine and Pharmacy Cluj-Napoca, Romania, 22/11/2013, Ref : 917

Study design
Randomized interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute idiopathic tinnitus

Interventions
Patients are randomly allocated to one of two groups. In one group the patients will be given melatonin plus four intra-tympanic dexamethasone injections, one on each 7 consecutive initial days. The patients will be given 3 mg of melatonin, 1 tablet nightly 1 to 2 hours before bedtime for 8 weeks. In the other group, patients will get melatonin tablets and intra-tympanic isotonic sodium chloride solution following the above mentioned schedule.

Follow-up: 3 months

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Melatonin, dexamethsaone

Primary outcome(s)
Patients selected as eligible will complete specific questionnaires at the beginning of the study and 3 months after the beginning of the treatment. Improvement in tinnitus should be assessed using three outcome measures:
1. Tinnitus loudness score (on a 10-point scale, 10 being loudest)
2. Tinnitus awareness score (percentage of the time the subject is aware of tinnitus)
3. Tinnitus Handicap Inventory (THI)
According to previous stated criteria, we define improvement as a >10% reduction of tinnitus awareness score, >2-point reduction of tinnitus loudness score, and >20-point reduction in THI. Cure is defined as a reduction in tinnitus awareness score to 0%.

Key secondary outcome(s))
Side effects of intratympanic dexamethasone:
1. Acute otitis media
2. Persistent eardrum perforation
3. Vertigo
4. Hearing loss

Completion date
01/03/2014

Eligibility

Key inclusion criteria

1. Male and female age ≥18 years
2. Willing to be assigned to any of the treatment groups
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients with identifiable causes of acute tinnitus

Date of first enrolment
02/12/2013

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Romania

Study participating centre
st Henri Barbusse nr 3-5
Cluj napoca
Romania
400616

Sponsor information

Organisation
Iuliu Hatieganu University of Medicine and Pharmacy Cluj-Napoca (Romania)

ROR
https://ror.org/051h0cw83

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Romania)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes