

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

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<b>Registration date</b> 16/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/12/2013	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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 Hațieganu University of Medicine and Pharmacy Cluj-Napoca, Romania, 22/11/2013, Ref : 917

**Study design**

Randomized interventional treatment 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 contact felicianchirtes@yahoo.com to request a patient information sheet

**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, dexamethasone

**Primary outcome measure**

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%.

## **Secondary outcome measures**

Side effects of intratympanic dexamethasone:

1. Acute otitis media
2. Persistent eardrum perforation
3. Vertigo
4. Hearing loss

## **Overall study start date**

02/12/2013

## **Completion date**

01/03/2014

# **Eligibility**

## **Key inclusion criteria**

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

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

60

## **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)

### **Sponsor details**

II-nd Department of Otolaryngology  
Str. Republicii nr. 18  
Cluj Napoca  
Romania  
3400

### **Sponsor type**

University/education

### **Website**

<http://www.umfcluj.ro/>

### **ROR**

<https://ror.org/051h0cw83>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded (Romania)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration