

# HYPERBARIC OXYGEN IN THE ACUTE TREATMENT OF SUDDEN IDIOPATHIC SENSORINEURAL HEARING LOSS

**RANDOMISED, PROSPECTIVE STUDY  
OF HYPERBARIC OXYGEN THERAPY  
AFTER FAILURE OF PREVIOUS  
MEDICAL TREATMENT**



## DATA RECORD FORM

*For obtaining a randomisation number*

*CALL +32 2 262 22 82 (24 / 24)*

*ask: "Randomisation Number for COST Study"*

*Alternatively: send e-mail to "medhyper@smd.be" with*

Subject line: RANDOMISATION NUMBER COST STUDY  
Message text: \* name of patient\*, \* name and number of center\*

*You will receive a reply within 2 days*

**RANDOMISATION NUMBER :** \_\_\_\_\_ **DATE OF ENROLLMENT:** \_\_\_\_\_

**COST B14 WG1: HYPERBARIC OXYGEN THERAPY AND SUDDEN SENSORINEURAL HEARING LOSS**

**1. BASELINE PRE-INCLUSION DATA**

a. Demographic data and previous medical history

SEX	M	F	
AGE			Years
SMOKING HABITS			Pack-Year
OCCUPATION			
HABITUAL NOISE EXPOSURE ?	YES	NO	
HISTORY OF VASCULAR DISEASE	Angina pectoris		YES NO
	Peripheral arterial disease		YES NO
	Deep / superficial vein thrombosis		YES NO
HISTORY OF PREVIOUS ENT DISEASE	Inner ear barotrauma		YES NO
	Sudden deafness (any ear)		YES NO
	Acoustic trauma		YES NO
	Mandibular joint dysfunction		YES NO
MECHANICAL NECK DYSFUNCTION	Cervical disc hernia etc.		YES NO
MEDICATIONS TAKEN THE WEEK BEFORE ONSET OF SUDDEN DEAFNESS			
PREVIOUS AUDIOMETRY AVAILABLE ?	YES	NO	

b. History of this Sudden Deafness

DATE OF ONSET	(day)	(mo)	(year)	= DAY 0
VERTIGO PRESENT	YES	NO		
TINNITUS PRESENT	YES	NO		
DATE OF FIRST MEDICAL EXAM	(day)	(mo)	(year)	
START OF INITIAL TREATMENT	(day)	(mo)	(year)	DAY 0 + ____
MEDICATIONS RECEIVED AS INITIAL TREATMENT				
Name of drug (generic name if possible)	Dosage + route (IV, oral)		Duration (Day x till y)	

**RANDOMISATION NUMBER :** \_\_\_\_\_ **DATE OF ENROLLMENT:** \_\_\_\_\_

## 2. INCLUSION – EXCLUSION CRITERIA

### a. Inclusion criteria (check)

Sudden sensorineural hearing loss (= transition from usual hearing to hearing loss in a period of 1-3 days maximum)	YES	NO
Loss of at least 30 dB HL in at least three frequencies compared to the contralateral ear	YES	NO
Mean Hearing Loss (sum of frequencies (250 + 500 + 1000 + 2000 + 4000 + 6000 + 8000) divided by 7) of less than -80 dB HL (i.e. no complete cophosis)	YES	NO
No significant compromise of hearing in the contralateral ear (loss of >30 dB HL in at least 3 frequencies), of whatever cause	YES	NO
Failure to respond (less than 10 dB HL mean improvement in the three most affected frequencies) to a "standard" treatment regimen, of at least 7 days and involving at least a scheme of high-dose corticosteroids	YES	NO
Delay of < 4 weeks before initiation of HBO	YES	NO
Age limits: >20 years, < 65 years	YES	NO

### b. Exclusion criteria (check)

Clear etiologic diagnosis: - viral infection, such as mumps etc. - trauma, including acute acoustic trauma and barotrauma - Ménière's disease - acoustic neurinoma - ototoxic medication - multiple sclerosis	YES	NO
Concomitant embolic or thrombotic arteriosclerotic disease (such as Transient Ischemic Attack, Cerebrovascular Accident, acute coronary occlusion, valvular emboligenic disease)	YES	NO
Situations where HBO may represent an additional risk: - recent (<2 years) spontaneous pneumothorax, - ear-drum or ossicle chain surgery, - acute upper respiratory tract infection, - untreated or insufficiently treated epilepsy, - concurrent treatment with radiotherapy or chemotherapy, - congenital spherocytosis, - psychotic disease, - pregnancy	YES	NO
Refusal to cooperate or sign the Informed Consent Form	YES	NO

**WHEN PATIENT CAN BE INCLUDED IN STUDY :**

**Sign Informed Consent Form  
Call for Randomisation Number**

**RANDOMISATION NUMBER :** \_\_\_\_\_ **DATE OF ENROLLMENT:** \_\_\_\_\_

### **3. BASELINE DATA RECORDINGS**

a. Clinical Examination

Arterial Blood Pressure	
Clinical ENT examination	

b. Laboratory Investigations

<b>Parameter</b>	<b>Result (+Measuring Unit)</b>	<b>Normal Value Range</b>
Red Blood Cell count		
Hemoglobin level		
Haematocrit		
Platelets		
White Blood Cell count		
- neutrophils		
- lymphocytes		
- eosinophils		
- basophils		
- monocytes		
- immature forms		
Erythrocyte Sedimentation Rate		
TPHA (T.Pallidum Haemagglutin.)		
Mumps IgG		
Mumps IgM		
<u>Other abnormal tests:</u>		

**RANDOMISATION NUMBER :** \_\_\_\_\_ **DATE OF ENROLLMENT:** \_\_\_\_\_

**COST B14 WG1: HYPERBARIC OXYGEN THERAPY AND SUDDEN SENSORINEURAL HEARING LOSS**

c. Paraclinical Examinations

Tonal Audiometry		Date:		
	<b>AIR CONDUCTION</b>		<b>BONE CONDUCTION</b>	
<b>Frequency (Hz)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>
<b>250</b>				
<b>500</b>				
<b>1000</b>				
<b>2000</b>				
<b>4000</b>				
<b>6000</b>				
<b>8000</b>				
Tympanometry with stapedius reflex		Date:	Result:	
Brainstem Evoked Potentials		Date:	Result:	
<b>Or:</b> Magnetic Resonance Imaging				

Subjective Symptoms Evaluation	Date:
<p>Mark TODAY'S severity of your tinnitus (ringing) on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark how much your tinnitus TODAY affects your daily life quality on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark TODAY'S severity of fullness in the ear on the following strip:</p> <p>0 <input type="text"/> 10</p>	

<b>RANDOMISATION NUMBER :</b> _____	<b>DATE OF ENROLLMENT:</b> _____
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**COST B14 WG1: HYPERBARIC OXYGEN THERAPY AND SUDDEN SENSORINEURAL HEARING LOSS**

d. Optional Paraclinical Examinations

<b>Laboratory Investigation</b>	<b>Date:</b>	<b>Result:</b>
Anti-nuclear antibodies (ANF)		
Anti-endothelial cell antibodies (AECA)		
Anticardiolipine antibodies (ACA)		
Anti-phospholipid antibodies		
Anti-serotonin antibodies		
Anti-ganglioside antibodies		
Cytomegalovirus (CMV) IgM		
Parainfluenza IgM		
Adenovirus IgM		
Red blood cell filtrability		
Plasma viscosity		
<b>Paraclinical Investigations</b>	<b>Date:</b>	<b>Result:</b>
Speech audiometry (proposed standard: DIN Norm)		
Tinnitus matching (tonal quality, loudness, masking level by white noise)		
Spontaneous otoacoustic emissions		
Eye fundoscopy		
Electronystagmography (in case of concomitant vertigo)		
Contrast-enhanced MRI (gadolinium contrast, T1 and T2 weighed images)		

<b>RANDOMISATION NUMBER :</b> _____	<b>DATE OF ENROLLMENT:</b> _____
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**4. EVALUATION -- DAY 6**

<b>Clinical ENT Examination :</b>		Date:	Result:	
<b>Tonal Audiometry:</b>		Date:		
	<b>AIR CONDUCTION</b>		<b>BONE CONDUCTION</b>	
<b>Frequency (Hz)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>
<b>250</b>				
<b>500</b>				
<b>1000</b>				
<b>2000</b>				
<b>4000</b>				
<b>6000</b>				
<b>8000</b>				
<b>Tympanometry with stapedius reflex</b>		Date:	Result:	

<b>Subjective Symptoms Evaluation</b>	Date:
<p>Mark TODAY'S severity of your tinnitus (ringing) on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark how much your tinnitus TODAY affects your daily life quality on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark TODAY'S severity of fullness in the ear on the following strip:</p> <p>0 <input type="text"/> 10</p>	

**EVALUATION OF SIDE EFFECTS: SEE LAST PAGE**

<b>RANDOMISATION NUMBER :</b> _____	<b>DATE OF ENROLLMENT:</b> _____
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**5. EVALUATION -- DAY 11**

<b>Clinical ENT Examination :</b>		Date:	Result:	
<b>Tonal Audiometry:</b>		Date:		
	<b>AIR CONDUCTION</b>		<b>BONE CONDUCTION</b>	
<b>Frequency (Hz)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>
<b>250</b>				
<b>500</b>				
<b>1000</b>				
<b>2000</b>				
<b>4000</b>				
<b>6000</b>				
<b>8000</b>				
<b>Tympanometry with stapedius reflex</b>		Date:	Result:	

<b>Subjective Symptoms Evaluation</b>	Date:
<p>Mark TODAY'S severity of your tinnitus (ringing) on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark how much your tinnitus TODAY affects your daily life quality on the following strip:</p> <p>0 <input type="text"/> 10</p> <p>Mark TODAY'S severity of fullness in the ear on the following strip:</p> <p>0 <input type="text"/> 10</p>	

<b>RANDOMISATION NUMBER :</b> _____	<b>DATE OF ENROLLMENT:</b> _____
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## OXYGEN LEVELS REACHED DURING HBO TREATMENTS

	Date of session	Mean PTcO <sub>2</sub> in subclavicular region (mmHg)	Oxygen % reached in mask (%)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

## SIDE EFFECTS EVALUATION

<b>Date:</b>		<b>Number of HBO treatments:</b>		
<b>Side Effects Evaluation</b>		<b>None</b>	<b>Moderate</b>	<b>Severe</b>
Pain in ear(s) during treatment				
Clinical signs of barotrauma (ear, sinus, tooth)				
Claustrophobia, anxiety				
O <sub>2</sub> toxicity (Mild = vomiting, Severe = convulsions)				
Other (describe below):				

<b>Date:</b>		<b>Number of HBO treatments:</b>		
<b>Side Effects Evaluation</b>		<b>None</b>	<b>Moderate</b>	<b>Severe</b>
Pain in ear(s) during treatment				
Clinical signs of barotrauma (ear, sinus, tooth)				
Claustrophobia, anxiety				
O <sub>2</sub> toxicity (Mild = vomiting, Severe = convulsions)				
Other (describe below):				

<b>RANDOMISATION NUMBER :</b> _____	<b>DATE OF ENROLLMENT:</b> _____
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**IF POSSIBLE, PERFORM A 3 MONTHS' EVALUATION**

**SEPARATE THESE LAST 2 PAGES FROM DATA RECORD FORM AND KEEP IT IN THE PATIENTS MEDICAL FILE UNTIL THREE MONTHS' EVALUATION**

**6. EVALUATION – THREE MONTHS**

<b>Total number of HBO treatments received :</b> (fill this in for all patients, also those who were included as "non-HBO" and who received HBO only after the 10 days study period)				
<b>Clinical ENT Examination :</b>	Date:	Result:		
<b>Tonal Audiometry:</b>	Date:			
	<b>AIR CONDUCTION</b>		<b>BONE CONDUCTION</b>	
<b>Frequency (Hz)</b>	<b>Left (dB HL)</b>	<b>Right (Db HL)</b>	<b>Left (dB HL)</b>	<b>Right (dB HL)</b>
<b>250</b>				
<b>500</b>				
<b>1000</b>				
<b>2000</b>				
<b>4000</b>				
<b>6000</b>				
<b>8000</b>				
<b>Tympanometry with stapedius reflex</b>	Date:	Result:		

<b>Subjective Symptoms Evaluation</b>	Date:
<p>Mark TODAY'S severity of your tinnitus (ringing) on the following strip:</p> <p>0 <input style="width: 500px; height: 20px;" type="text"/> 10</p>	
<p>Mark how much your tinnitus TODAY affects your daily life quality on the following strip:</p> <p>0 <input style="width: 500px; height: 20px;" type="text"/> 10</p>	
<p>Mark TODAY'S severity of fullness in the ear on the following strip:</p> <p>0 <input style="width: 500px; height: 20px;" type="text"/> 10</p>	

THIS EVALUATION IS NOT PART OF THE STUDY – THE BELOW INFORMATION IS ONLY ASKED TO MAKE SEPARATE ANALYSIS POSSIBLE

**RANDOMISATION NUMBER :** \_\_\_\_\_ **DATE OF ENROLLMENT:** \_\_\_\_\_