COST B14 "Hyperbaric Oxygen Therapy" WORKING GROUP 1

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

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AGREEMENT

Between **COST Action B14 Working Group 1**
Acting as Research Team Coordinator (RTC) and Monitoring Instance

Represented by : Dr Alain Barthélémy, WG Secretary
Hôpital Salvator - Centre Hyperbare
249, Boulevard de Ste Marguerite
BP 51 F-13274 Marseille Cedex 9

hereafter named: the RTC

And Dr. _____
FULL NAME AND SURNAME

_____
FULL ADDRESS OF INSTITUTION

_____

_____

hereafter named: the Investigator

Is agreed the following:

A. PARTICIPATION AGREEMENT

1. The Investigator agrees to participate in the prospective controlled trial on the efficacy of hyperbaric oxygen therapy in the treatment of sudden sensorineural hearing loss, as described in the 'ad hoc' research protocol. This protocol is available in print to the investigator as part of the Investigator Brochure, and is accessible via the Internet on www.oxynet.org

2. The investigator engages to strictly follow the protocol as described, and to enroll only those patients who comply with all inclusion and exclusion criteria.

3. The investigator engages to enroll a minimum of 20 patients during the two year study period. If this seems an unrealistically high number, the investigator should not take part in the study.

4. The Investigator agrees to be mentioned in the list of participating investigators, in all official written reports regarding the study, including the final publication.

B. INDEMNITY AGREEMENT

5. The present study protocol has been conceived and will be conducted on a voluntary basis. There is no financial support from the pharmaceutical industry, nor from any supra-national governmental of scientific organisation. There will be no financial benefit from enrolling patients in the study. However, the Investigator is free to independently explore possible funding for his participation in the study (e.g. from governemental or research-oriented institutions). These however will only be accepted after consensus agreement from the RTC. In the case a substantial financial contribution has been made from such an instance, from which not only the Investigator but also the other investigators have benefited, the said instance will be mentioned on written reports as 'sponsor' of the study. Multiple sponsors can thus be accepted. The acceptance of such a 'sponsor' is of the sole decision of the RTC.

6. The Investigator furthermore engages to provide hyperbaric and placebo treatments free of charge to patients enrolled in the study protocol.

C. SOURCE DATA VERIFICATION

7. Patient trial records should be kept for a period of at least 5 years after the conclusion of the trial. The Investigator agrees to have the patient trial records at the disposal of the RTC if necessary.

8. The Investigator will designate a responsible person for the archiving of the patient trial records, and will designate a replacement of this person in case the first becomes unavailable permanently. The initial trial records 'keeper' will be

_____
FULL NAME AND SURNAME

D. EXPLOITATION OF TRIAL DATA AND RESULTS

9. Use of trial data for any research purpose will be restricted to the strict and written approval of the RTC, even in the case of the Investigator's own patients. Analysis and publication of data will in any case be authorised only after the main publication regarding the study outcome has been published according to the requirements of the COST Action.

Intermediate data analysis, or analysis of a subset of data without direct pertinence to the subject of the study, is encouraged, but will likewise have to be submitted to the written approval of the RTC.

10. Publication of study results: a comprehensive study report will be submitted to a major peer-reviewed medical journal, in accordance to the requirements of the COST Action. Authorship of papers will include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper. Authors should have participated sufficiently in the research to take public responsibility for the content. The guidelines of the International Committee of Medical Journal Editors will be adhered to (Reference: International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *Med Edu*c, 1999; 3(1): 66-78). Principal authors will be the members of the RTC, as well as any other investigator willing to make a substantial contribution to the study. All investigators will be formally acknowledged in all study reports and papers.

Signed by both parties in duplo. One copy will be kept by the RTC, the second copy will be filed in the Investigator Brochure.

The Investigator will receive the following Treatment Centre Reference number: _____

For the RTC:

_____	_____	_____
FULL NAME	SIGNATURE	DATE

The Investigator:

_____	_____	_____
FULL NAME	SIGNATURE	DATE

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