Clinique André Renard réseau Solidaris

Predictability of OSA with a Subjective Screening Scale

Predictive Value of OSA Based on the Evaluation of the Subjective Feeling of the Air Flow Through Airways, a Randomized Controlled Study

id: OSASSS1 - NCT:06092710

Mai 11, 2025

About the study protocole:

The oropharynx, due to its specific layout in humans, is unstable under the effect of inspiratory depression during ventilation. Continuous control of the oropharyngeal lumen is necessary to ensure optimal ventilation.
The combined role of all the pharyngeal dilator muscles and the muscles constituting the pharyngeal groove is essential for maintaining the patency of the pharyngeal upper airway. The action of these muscles allows for the postural adjustment of the pharyngeal cavities and the rigidity of the entire pharyngeal muscular groove.
The permeability of the upper airways is therefore largely dependent on optimal tone of the muscles constituting the walls of the upper airways. The management of the tone of these muscles is possible thanks to the numerous mechanosensory receptors present in the upper airways. There are many of them, among which some are sensitive to changes in shape, the passage of air, variations in temperature, pressure, etc. The opening reflex of the upper airways depends on the integrity and quality of these receptors. Several known factors can lead to an alteration of these receptors: vibrations of the soft palate, edema, inflammation, hypoxia, GERD, drying of the mucous membranes, postnasal drip, etc.
In sleep disorders, the excitability threshold of these receptors can vary depending on the extent of VAS resistance (SRAVAS), or even collapse (OSA). It is possible that the sensitivity of these receptors is exacerbated in cases of SRAVAS and mild OSA and reduced or even inhibited in severe forms of OSA.
Numerous parietal factors modify the volume and permeability of the pharynx (pharyngeal lumen) and act through different mechanisms:
- Modification of the pharyngeal lumen in the transverse and sagittal dimensions
- Modification of transmural parietal tension (longitudinal tension) and therefore of the compliance of the pharyngeal wall by the passive and active tension of the pharyngeal muscles (tonic, phasic)
Considering the permeability of the pharynx, we can identify biomechanical parameters that increase resistance to the passage of air in the upper airways (aggravating parameters) and others that decrease resistance (facilitating parameters).

Aggravating factors:
- Supine position
- Altered state of consciousness (first sleep stage)
- Mouth breathing and loss of lingual-palatal and labial-labial contact
- Passive craniocervical flexion

Facilitating parameters:
- Cephalocervical extension
- Mandibular advancement
- Tongue protraction
- Efficient nasal ventilation

These considerations allow us to establish an examination protocol to attempt to answer the following questions:
- Can the subject consciously perceive variations in airflow/or intraluminal pressure in the upper airways caused by the various aggravating and facilitating parameters?
- Can the sensations of ventilatory flow/intraluminal pressure felt by the subject constitute a complementary tool for screening for obstructive sleep disorders?

The goal of the clinical examination is to cause instability of the oropharyngeal mechanics. This instability can cause a modification of the pharyngeal lumen and a modification of the resistance of the VAS to the pressure linked to the ventilatory flow. These will lead to a modification of the inspiratory pressure gradient and stimulate the mechanoreceptors located in the VAS. The responses to a questionnaire by subjects who present sleep disorders exposed to these variations in resistance (aggravating or facilitating) on their subjective feeling allows the establishment of a perception scale which, compared to a control group without sleep disorders, will determine if the sensitivity of the inputs is comparable between the groups and if a tool for screening sensory inputs is possible.

Protocol:

The questionnaires to assess patients' pharyngeal ventilatory perceptual potential/the quality of spontaneous nasopharyngeal perception during ventilation are administered when patients come to the consultation to request the results of the pharyngeal ventilatory perceptual analysis. The examiners are blinded, unaware of the results. Patients are randomly assigned according to their order of arrival. The first questionnaire consists of 7 items selected to aggravate or facilitate upper airways permability (supine position, modified state of consciousness with muscle relaxation, tongue posture, cephalic flexion, cephalic extension, mandibular protraction, nostrils aperture). This first questionnaire try to evaluate if all subjects are able to feel aggravating or facilitating factors by on/off answers. The second questionnaire consists of 18 items related to upper airway collapsibility. Each item concerns the aggravating or facilitating factors perceived by the patient or the therapist with clinical maneuvers, factors known to be unfavourable to the permeability of the upper airways (snoring, oral ventilation, tonsils, dento-skeletal class, etc.), as well as two questionnaires used in the sleep laboratory of the André Renard clinic (Epworth Sleepiness Scale and FFF questionnaire).
For each of these items, the patient's or practitioner's response will be noted.

Performing the examination:
- Sensory-motor awareness of nasal and pharyngeal breathing (patient in a seated position): explain to the patient what to observe and feel and where (soft palate, tonsils, vibration during snoring, etc.)
- Read the questionnaire to the patient: it must be understood
- Ask the patient to answer each item and record the response.

The examination lasts approximately 20 minutes.
This examination requires patient involvement but carries no risks or side effects.


N≥55 subjects with PSG, Epworth, Pichot, FFF scales ==> SAOS validated and severity stage determined
recruitment
N≥55 subjects after Epworth, Pichot, Berlin, FFF scales ==> negativity of SAOS
N= « x » subjects with SAOS
inclusion
N≥ (110 - x) subjects without SAOS
Randomized by 3 neurologists from Clinique André Renard
Subjective sensitivity protocol by 2 « blinded » manual therapist
N≥110
primary outcomes: Do clinic patients and controls perceive the expected variations in aggravating and facilitating maneuvers?
if no = end of the study
Subjective screening protocol by 2 « blinded » manual therapist
N≥110
primary outcomes: Does the clinical screening tool based on a score using the subjective perception of airway collapsibility make it possible to identify subjects with OSA and subjects without OSA?
if no = end of the study
N≥ « X »
secondary outcomes: Is it possible to predict the severity of OSA according to the score obtained by the clinical screening tool using the subjective perception of upper airway collapse?
if no = end of the study
N≥ « X »
secondary outcomes: Is it possible to determine indications for therapeutic tools based on items assessed during clinical screening using the subjective sensitivity of upper airway collapsibility?

STATISTATICAL ANALYSIS PLAN
(translation of the Statistical analysis report download in SAP section from an independent Biostatistician: Laurent Massart, MyStat.be)

Software used for analysis: R version 4.4.1(R Core Team (2024). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/) and Microsoft Excel for manipulating and preparing the data tables. data files used and appended: d1_final.csv, d2_final.csv
1 - d1_final.csv: sensitivity parameters taken from 112 patients
2 - d2_final.csv: parameters taken from 101 patients (excluding CHR patients considered normal after polysomnography)
Discrete variables for classification into groups :
- STATUS3: 2 categories: healthy patients (= non-CHR control patients and normal CHR patients) and pathological patients (= CHR patients affected to varying degrees)
- STATUS4: 4 categories: control patients (= non CHR), normal patients (= CHR N), mild symptom patients (= CHR SL), moderate symptom patients (= CHR SM) and severe symptom patients (= CHR SS).

A. Descriptive statistics (based on file n°1 - sensitivity)

B. Descriptive statistics (based on file n° 2 - predictive score)

C. Normality tests for intermediate and final scores

- Parameter ST1 (SubTotal1) = aggravating parameters
Shapiro-Wilk normality test
- Parameter ST2 (SubTotal2) = facilitating parameters
Shapiro-Wilk normality test
- Parameter ST1+ST2 (SubTotal1+ SubTotal2) = subjective sensitivity of patients
Shapiro-Wilk normality test
- Parameter ISF (Intermediate Final Score) = subjective sensitivity of patients and practitioner
Shapiro-Wilk normality test
- Parameter TFS (Total Final Score) = subjective sensitivity of patients and practitioner + valuable factors
Shapiro-Wilk normality test

D. Spearman correlation tests between final scores and certain variables

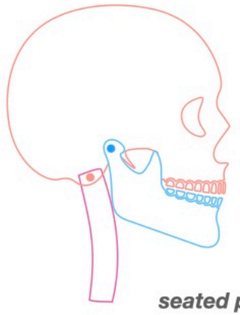
E. Non-parametric tests on patient sensitivity :
Given the non-normal distribution of the various variables other than IFS and TFS, non-parametric tests (based on the median of the data) were applied to analyse the differences between the groups (according to the STATUS3 and STATUS4 classification criteria). To analyse any differences in sensitivity between patient groups, Kruskal-Wallis tests were applied. In this type of analysis, having a p-value greater than 1% and ideally greater than 5% would indicate the absence of differences between groups.
Then, to see if the median of a particular group is different from 0 (= no sensitivity: not feeling the differences in airflow induced by the different tests given by the operator), Wilcoxon tests were performed on each group of data. If the p-value is small (less than 5%, ideally less than 1%), the null hypothesis that the score is identical to 0 is rejected. In this case, it means that the patients in the test group feel the differences in airflow depending on their position. This is the case for all the patient groups tested on ST1, ST2 and ST1+ST2.

F. Parametric tests on the prediction of patients' pathological status (SFI and SFT scores):
For these analyses, as the IFS and TFS scores follow a normal distribution, ANOVAs (analyses of variance) were performed. For discrete variables with more than 2 levels of value (STATUS4), a post-hoc 2-to-2 comparison analysis was performed (Tukey) to see which level of the variable differed from one another. Significant values are highlighted in bold red.

G. Determination of cut-off values for IFS and TFS:
The Cutoff_final txt file includes the various sensitivity and specificity calculations as well as the Youden index in order to determine the best cut-off value (largest Youden). The ROC curves allow the values in the file to be appreciated graphically.

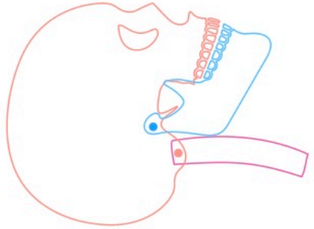
Upper rhino-oro-pharyngeal airway permeability - Subjective neuro-sensory evaluation

Sensory awakening of the nasopharyngeal ventilatory space:
- awareness of mandibular, lingual and labial posture
- simulation of snoring to make the soft palate vibrate
- swallowing to feel the pharynx rise and contract
- search for descriptions related to the subject's experience (angina to locate the tonsils, etc.)



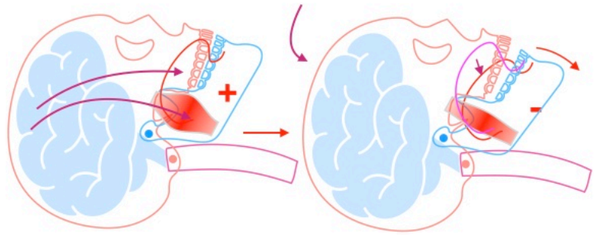
seated position

Beware of false negative bias: a response based on another interoceptive reference point, for example body comfort in the dorsal position —> therapist verification



Supine position

Therapist's voice + manual induction



Beware of false negative bias: a response based on another interoceptive reference point, for example muscular comfort in relaxation, instead of the sensation of air passing through the upper airways —> therapist verification

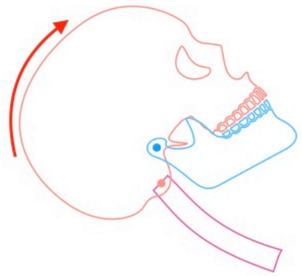
0

1 *AM*

Modified state of consciousness (overall relaxation)

2 *AM*

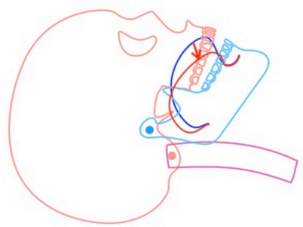
3 *AM* *Cephalic flexion*

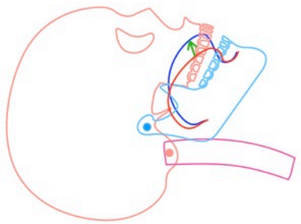


Beware of false negative bias
- active head flexion
- associated automatic mandibular protraction
—> therapist verification

FM 4 . 4 *AM*

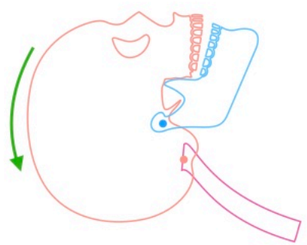
Lingual Position :
Upper-anterior tongue to lower tongue (= aggravation)
or
lower tongue to upper-anterior tongue (= facilitation)





5 *FM*

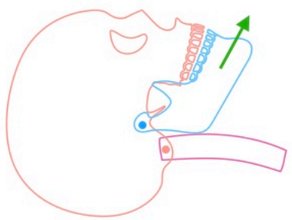
Cephalic Extension



Beware of false negative bias
- neck discomfort —> therapist verification

6 *FM*

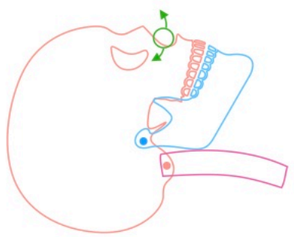
Mandibular Protrusion



Beware of false negative bias
- excessive advancement —> therapist verification

7 *FM*

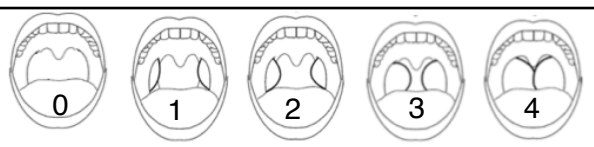
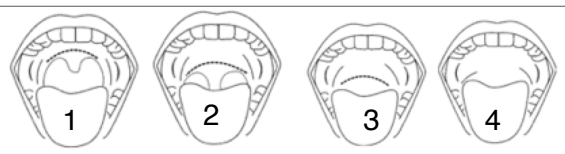
Nostrils aperture (manual or nasal dilators)

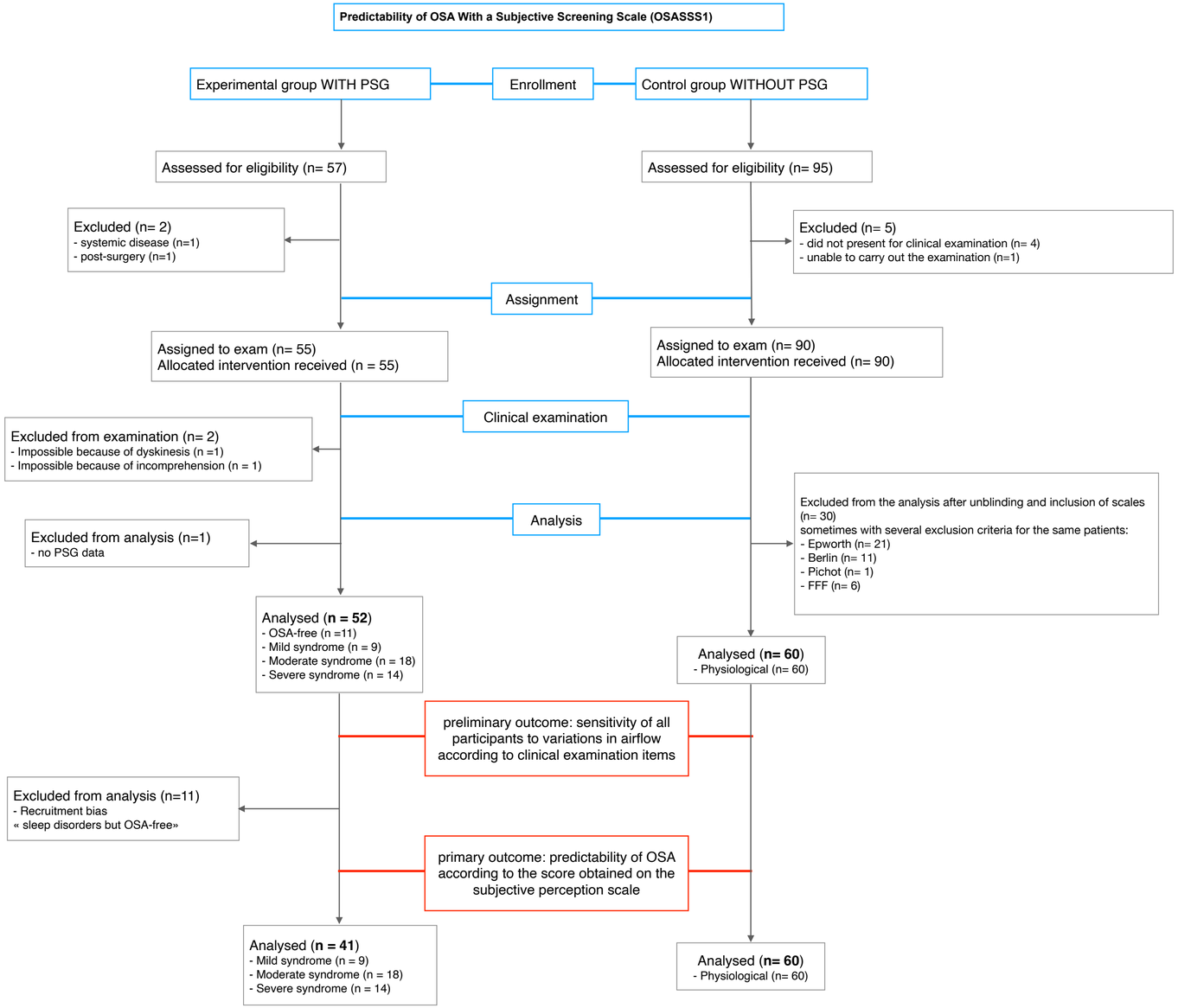


Aggravation Maneuver = AM

Facilitating Maneuver = FM

Assessment of oro-pharyngeal sensitivity				
Date :	Name:		age:	
Tests	*Items*	*Aggravation or facilitation felt= **1*** *No aggravation or no facilitation felt= **0***	***Score***	
			1	**0**
Aggravation maneuver	*1*	*Supine position*	☐	☐
Aggravation maneuver	*2*	*Modified state of consciousness (overall relaxation)*	☐	☐
Aggravation maneuver	*3*	*Cephalic Flexion*	☐	☐
Aggravation or Facilitation maneuver	*4*	*Upper-anterior tongue to lower tongue (= **aggravation**) or lower tongue to upper-anterior tongue (= **facilitation**)*	☐	☐
Facilitation maneuver	*5*	*Cephalic Extension*	☐	☐
Facilitation maneuver	*6*	*Mandibular protrusion*	☐	☐
Facilitation maneuver	*7*	*Nostrils aperture*	☐	☐
Total Score			**… / 7**	
Comments :				

Upper rhino-oro-pharyngeal airway permeability - Subjective neuro-sensory evaluation						
Date :	Name :		age: IMC:			
Tests	*Items*		*Scores*			
			0	*0,5*	*1*	*2*
Aggravation maneuver	*1*	*Supine position: aggravation=1 / no aggravation= 0*	☐		☐	
Aggravation maneuver	*2*	*Modified state of consciousness (overall relaxation) aggravation=1 / no aggravation= 0*	☐		☐	
Aggravation maneuver	*3*	*Cephalic flexion: aggravation at the start of flexion (≤ 6°)=2 / in the middle of flexion (7—>10°)=1 / at the end of flexion (≥11°)=0*	☐		☐	☐
Facilitation maneuver	*4*	*Cephalic extension: facilitation from the start of extension (≤ 6°)=2 / in the middle of extension (7—>10°)=1 / at the end of extension (≥11°)=0*	☐		☐	☐
Facilitation maneuver	*5*	*Measurement of range: amplitude between cephalic flexion and extension: reduced (≤12°)=2 / medium (13->20°)=1 / large (≥21°)=0*	☐		☐	☐
Facilitation maneuver	*6*	*Mandibular advancement: Physiological=2 / Tooth butt =1 / Anterior crossing=0.5 / no facilitation= 0*	☐	☐	☐	☐
Therapist observation	*7*	*Therapist palpation of the contraction of the buccal floor on inspiration at rest yes=2 / no=0*	☐			☐
Therapist observation	*8*	*Sound perception of ventilation by the therapist: yes=1 / no=0*	☐		☐	
Intermediate Final Score (IFS): low risk of OSA ≤ 7.5 / risk of OSA ≥ 8						**… / 13**
Aggravated situation	*9*	*Low lingual posture in supine position : yes=2 / no=0*	☐			☐
Subjective perception of nasal permeability	*10*	*Do you regularly have difficulty breathing through your nose? yes= 1 / no= 0*	☐		☐	
Subjective perception of snoring	*11*	*Do you snore at night? yes=1 / no=0*	☐		☐	
Subjective perception of daytime ventilation patterns	*12*	*During the day, you breathe mainly: through the mouth=1 / mixed nose-mouth=0,5 / through the nose =0*	☐	☐	☐	
subjective perception of nocturnal breathing patterns	*13*	*At night, you breathe mainly: through the mouth=2 / mixed nose-mouth=1 / through the nose =0*	☐		☐	☐
Therapist observation	*14*	*Dento-skeletal class: class I or III = 0 / class II = 1*	☐		☐	
Therapist observation: Tonsils: grades 0-1-2 =0 / grades 3-4 =1	*15*	*Quote :* 	☐		☐	
Therapist observation: Mallampati: grade 1-2 =0 / grade 3-4 =1	*16*	*Quote :* 	☐		☐	
Epworth Sleepiness Scale	*17*	*score: ≤ 8 =0 / 9–>14 =1 / ≥15 = 2*	☐		☐	☐
FFF questionnaire	*18*	*score ≤ 10 =0 / ≥11 =1*	☐		☐	
Final Total Score (FTS): low risk of OSAS ≤10 / high risk of OSAS ≥11						**… / 26**
Comments :						



Study process adapted from the CONSORT 2010 flowchart.

STUDY GROUP: The final sample included 41 patients diagnosed with OSAH (mild= 9, moderate=18; severe= 14).
The study sample included 13 women and 28 men, with a mean age of 49.30 years, and a mean body mass index (BMI) of 30.70 kg/m2.

CONTROL GROUP: The final sample included 60 patients without OSA based on subjective scales used in sleep medicine in Liège (Epworth, Berlin, Pichot, FFF).
The study sample comprised 20 men and 40 women, with a mean age of 41.76 years and a mean body mass index (BMI) of 22.78 kg/m2.

Andre Renard Ethics Committee **ID: OSASSS1 - NCT: 06092710**

Predictability of OSA with a Subjective Screening Scale

Predictive Value of OSA Based on the Evaluation of the Subjective Feeling of the Air Flow Through Airways, a Randomized Controlled Study

Herstal, February 3, 2023

Favorable Opinion

Composition of the Ethics Committee:

- - Dr. Anthony Nguyen - Vascular Surgeon
- - Dr. Ayse Acar - External General Practitioner
- - Dr. Chantal Bully - Palliative Care
- - Dr. Dominique Courard - Anesthesiologist
- - Dr. Natacha Noël - Geriatrician
- - Maître Jean-Luc Wenric - Lawyer at the Liège Bar
- - Ms. Caroline Doppagne - Hospital Mediator
- - Ms. Céline Nihoul - Psychologist
- - Ms. Dominique Klein - Social Worker
- - Ms. Emeline Baptiste - Hospital Pharmacist
- - Ms. Jennifer Derison - Nurse in the Intensive Care Unit

Subject:

"Predictive Value of OSA Based on the Evaluation of the Subjective Feeling of Airflow Through the Upper Airways"

Dear Dr. Lacroix,

After reviewing the informed consent and receiving the responses to the questions raised during the meeting on 12/01/2023, I inform you that the local Ethics Committee of the Andre Renard Clinic has issued a favorable opinion regarding the study:
"Predictive Value of OSA Based on the Evaluation of the Subjective Feeling of Airflow Through the Upper Airways."

The committee considers that the study mentioned above complies with medical ethics rules. The study may be carried out.

Please accept, Dr. Lacroix, the expression of my best regards.

Dr. Anthony Nguyen, MD, PhD
Chairman of the Ethics Committee
Andre Renard Clinic
anthony.nguyen@cliniqueandrerenard.be

Certificate of consent to participate in a study protocol at the Sleep Medicine Center (CMS):
"RHINO-OROPHARYNGEAL UPPER AIRWAY PERMEABILITY – SUBJECTIVE NEUROSENSORY ASSESSMENT":

Investigators: Alain PIRON and Cédric GARCION, osteopaths
Promoters of the study: Alain LACROIX and Bassam CHAKAR, Ivan SELAK, neurologists from the CMS

I, the undersigned, Miss./Mrs./Mr…….

date of birth ……/..../…. ....

freely and voluntarily **accept to participate** in the protocol referenced above, coordinated by Alain PIRON and Cédric GARCION supervised by Drs Alain LACROIX, Bassam CHAKAR and Ivan SELAK.

Being heard that : :

- The investigators who informed me and clearly answered all my questions, told me that my participation is free and that I can withdraw from the protocol at any time.
- I was previously given an information note on this protocol, specifying its purpose, its methodology, its expected benefits and its foreseeable risks.
- I will be able to have communication from the investigators, during or at the end of the protocol, of the information they hold concerning my health.
- I am perfectly aware that I can withdraw my consent to my participation in this protocol at any time, whatever my reasons and without bearing any responsibility. In this case, I undertake to inform the investigators.
- I may request additional information from the investigators at any time.
- If I wish, at the end, I will be informed by the investigators of the overall results of this study.
- My consent in no way relieves investigators and supervisors of all their responsibilities and I retain all my rights guaranteed by law.

Date : Patient Signature :
Signature of the investigators, who attest to having fully explained to the person signing the purpose, the modalities as well as the potential risks of the study. Date : Name and Signature :

This document must be produced in 2 original copies: the first must be kept by the investigator and the second is given to the person giving consent.