INFORMED CONSENT FORM

Assessment of the effect of hypoglossal nerve stimulation (HNS) therapy on upper airway collapsibility during drug-induced sleep endoscopy

Official title of the trial: *Assessment of the effect of hypoglossal nerve stimulation (HNS) therapy on upper airway collapsibility during drug-induced sleep endoscopy*

Trial number: *EDGE-004441*

Sponsor(s) of the trial: *Antwerp University Hospital, Drie Eikenstraat 655, 2650 Edegem*

Site name: *Universitair Ziekenhuis Antwerpen*

Main address of site: *Drie Eikenstraat 655, 2650 Edegem*

Who can I contact in case of questions?

Name	Function	In case of	Contact details
Vanderveken, Olivier	Principal Investigator of the site	Information, problems or concerns	0032 3 821 3385 nko@uza.be
	The trial staff	Information, problems, concerns	0032 3 436 82 47 eldar.tukanov@uza.be
	Emergency contact	Emergency	0032 3 821 3385
	Patient rights ombudsman	Concerns relating to your rights as a participant in a trial	0032 3 821 31 60 ombudsdienst@uza.be
AMMA Verzekeringen, Kunstlaan 39/1, 1040 Brussel	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	Policy nr: 1887617 Address: Kunstlaan 39/1, 1040 Brussel Phone nr.: 02 209 02 00
	Data protection officer of the **site**	Questions relating to the confidentiality of your data	0032 3 821 52 88 E-mail: dpo@uza.be
	Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	+32(0)2274 48 00 E-mail: contact@apd-gba.be

- *To manage complaints not resolved by the investigator, you can contact the study centre ombudsman at the above address.*
- *According to the GDPR, you have the right to access the processing of your data. For questions about this, you can contact the Study Centre's Data Protection Officer at the above address.*
- *You also have the right to lodge a complaint about the way your data are processed with the Belgian supervisory authority responsible for compliance with data protection legislation: Data Protection Authority (GBA), above.*

Version No: 1.0

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THE TRIAL AT A GLANCE

You are invited to voluntarily participate in a clinical trial in which, with the help of a sleep endoscopy (drug-induced sleep endoscopy, drug-induced sleep endoscopy, DISE), we aim to investigate the effect of hypoglossal nerve stimulation (HNS) on the collapsibility of the upper airways.

You are invited to participate in this trial because you have been treated with HNS for obstructive sleep apnea (OSA) for one year.

The effect of HNS on the underlying disease mechanisms of OSA is still unknown. However, this is of great importance for better understanding and future improvement of this therapy. If we have all this information, it may improve treatment and bring us a step closer to personalized therapies.

The purpose of this trial is to examine the effect of HNS on the collapsibility (the tendency of the upper airways to collapse) in patients with OSA. To do so, findings during a sleep endoscopy will be evaluated, supplemented by additional measurements taken during the procedure. This procedure is performed about one year after the start of HNS treatment as part of the treatment with HNS.

A secondary aim is to compare these results between patients who respond to treatment and those who do not. For this, data from sleep studies (polysomnography, PSG) before treatment and after one year of treatment are needed. In addition, we will include the results of the pre-treatment sleep endoscopy. In this way, the relationship between the collapsibility of the upper airways and successful HNS treatment can be investigated.

Before you agree to participate in this trial, we want to fully inform you about the trial, the organizational implications, and the possible risks and benefits, so that you can make your own decision about whether or not to participate. This process is known as giving "informed consent."

In total, you will need to come to the hospital twice. One visit will be for your standard one-year follow-up sleep study with HNS. The other visit will be for an additional sleep endoscopy after one year of HNS treatment, scheduled the day after the sleep study. Both examinations are part of routine care in patients with an HNS and are not performed as part of this study.

During the sleep endoscopy, additional measurements will be performed while you sleep. The trial-specific procedures (additional measurements during sleep endoscopy) will not be charged to you.

The sponsor of this trial has taken out insurance for the trial. The data collected during this trial will be treated confidentially.

It is not permitted to participate in another clinical trial at the same time without informing the trial physician or their staff.

The authorities and an ethics committee have evaluated this trial. They have approved it, but this does not mean you are obliged to participate. Participation is entirely voluntary, and you may stop at any point during the trial. The trial physician will fully understand your decision and will continue to provide you with the same care as before.

Now that you have an idea of what this trial involves, we ask that you read all the pages carefully. It is important that you take the time to read and understand all the information. Please feel free to discuss the trial with someone you trust (such as a friend, family member, or your general practitioner). The trial physician and their team are also available to help you if anything is unclear. It is their task to ensure that you fully understand all the information.

If you agree to participate, both you and the trial physician must sign the informed consent form. You will receive a signed copy of the form with the date included.

CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS WHEN PARTICIPATING

1. Why are we doing this trial

This clinical trial (further on referred to as “trial”) will evaluate the effect of treatment with hypoglossal nerve stimulation on the underlying mechanisms of obstructive sleep apnea. Several disease mechanism parameters are known to be associated with obstructive sleep apnea. However, currently only the location of upper airway collapse is examined in clinical practice using sleep endoscopy. Of the other parameters, the so-called airway collapsibility is a widely studied mechanism. This parameter indicates how easily the patient's upper airway tends to collapse and can be checked with additional measurements during sleep endoscopy.

The aim of this trial is to investigate the effect of hypoglossal nerve stimulation on collapsibility during a sleep endoscopy. This information will give us a better understanding of how the hypoglossal nerve stimulator works. In the long term, we hope that this knowledge will enable us to tailor treatment even better to the right patients and make care even more personalized.

2. Why am I being asked to take part?

You are being asked to take part in this trial because you have been treated with a hypoglossal nerve stimulator (type Inspire) for obstructive sleep apnea for one year.

The researcher or study staff will discuss the conditions for admission to the study with you.

3. Do I have to take part in a trial?

Your participation in a trial is voluntary and must remain free of any coercion. This means that you have the right not to take part in the trial or to withdraw at any time without giving a reason, even if you previously agreed to take part. Your decision will

not affect your relationship with the investigator or your treating physician nor will it affect the quality of your future medical care.

If other treatments are available for your disease/condition, the investigator or his/her delegate will discuss these treatments with you.

4. What will happen during the trial?

Approximately 21 participants will be involved in this trial. Your participation is expected to last at least two months and at most six months. In total, you will need to come to the hospital four times as part of routine care with hypoglossal nerve stimulation. You will not have any additional visits as part of the trial.

In the following text, you will find the treatments and examinations you will undergo. The additional measurements during the sleep endoscopy (not the sleep endoscopy itself) are trial-specific, the others belong to the standard treatment for your condition. The treatments and examinations that are trial-specific will be covered by the sponsor and will not be charged to you. The treatments and examinations that are part of your standard care will either be billed to you or reimbursed by your health insurance (Belgian social security).

Please contact the trial staff for more details, or if you are not affiliated with a health insurance fund (Belgian social security).

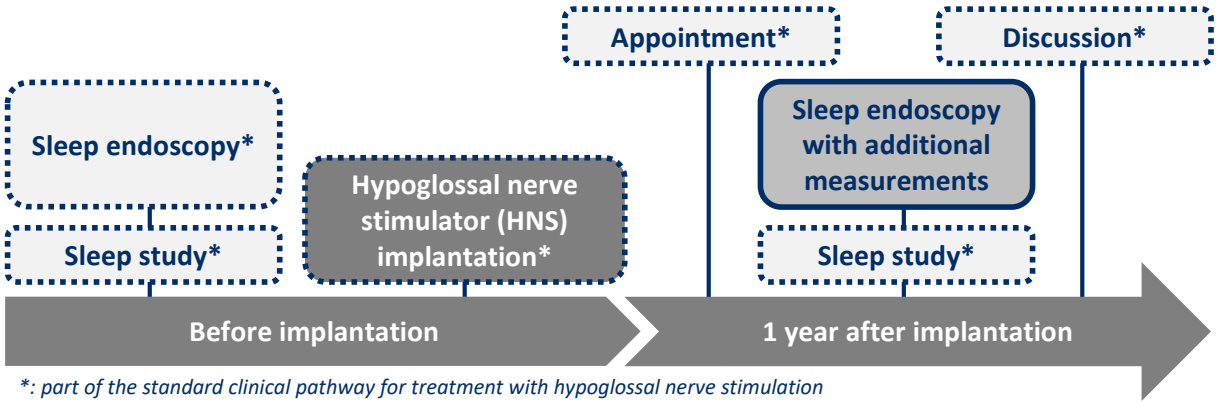

Figure 1: Trial timeline

<u>Visit 1 (standard clinical) – One-year follow-up appointment</u>

During this visit, informed consent will be obtained, and your medical history and demographic data will be collected, including height, weight, sex, and age. In addition, data from your previous sleep apnea assessments (pre-operative sleep study and sleep endoscopy) will be gathered.

Your hypoglossal nerve stimulator will be interrogated.

Following this, the follow-up examinations will be scheduled, including the sleep study (standard clinical) and the sleep endoscopy (partially standard clinical, partially ttrial-specific).

This visit is part of standard clinical practice.

Visit 2 (standard clinical) – One-year follow-up sleep study

During this visit, the one-year follow-up sleep study will be performed to monitor the effect of your hypoglossal nerve stimulator on sleep. This examination is part of routine follow-up for patients with a hypoglossal nerve stimulator.

This visit is part of standard clinical practice.

Visit 3 (partially standard clinical, partially trial-specific) – One-year follow-up sleep endoscopy

After the sleep study, a sleep endoscopy with additional measurements will be carried out. During this examination, you will be briefly put to sleep so that the upper airways can be examined with an endoscope inserted through the nose. You have already undergone this procedure prior to the implantation of the hypoglossal nerve stimulator and is part of standard clinical practice in patients with a hypoglossal nerve stimulator.

The procedure consists of a sleep endoscopy performed under one-day admission, in which muscle relaxation is induced with medication, resulting in an artificial sleep-like state. Throughout the procedure, you will be continuously monitored by an anesthesiologist. Unlike the examination you underwent before the implantation of the hypoglossal nerve stimulator, several additional parameters will be measured this time. To capture these parameters, you will wear a CPAP mask during the procedure. In addition, small sensors will be placed on your head to measure sleep, and two belts will be placed around your chest and abdomen to measure your breathing effort. Because of these additional assessments, the procedure will last about 30 minutes longer.

The following measurements will be carried out during this procedure:

- EEG: electroencephalography. This measures your brain activity during sleep, making it possible to determine in which stage of sleep you are at any given time. This is done by placing electrodes on the scalp with washable gel, as in the recent sleep study you have already undergone.
- EOG: electrooculography. This measures eye movements during sleep. It helps determine which sleep stage you are in at any moment. Electrodes are placed around the eyes on the head, just like in your recent sleep study.
- Chin EMG: electromyography. This measures muscle activity in the chin area, which also helps define the sleep stage. This is done with an electrode placed on the chin, as in your recent sleep study.
- Respiratory effort. To measure your breathing effort, two conductive belts will be placed around your chest and abdomen. These provide information on the effort you make to breathe, as in your recent sleep study.
- Breathing pattern. To measure your breathing, you will wear a mask through which you can breathe normally.
- Endoscopy. To visualize your airway, a small camera will be inserted through the nose. This is standard in a sleep endoscopy and not performed specifically for the clinical trial.

This visit is part of standard clinical practice, the additional measurements are study-specific.

Visit 4 (standard clinical) – Discussion of results

During this visit, the results of the sleep study and the sleep endoscopy will be discussed.

This visit is part of standard clinical practice.

5. Will I benefit from the trial?

The information obtained during this trial may contribute to a better understanding of the disease mechanism of obstructive sleep apnea and its association with hypoglossal nerve stimulation. This will lead to improved development of this treatment and better selection of patients.

6. What are the possible risks and discomforts of taking part?

6.1. What are the possible risks or discomforts of the examinations during the trial?

This trial collects data from examinations that are part of the standard clinical pathway for patients with a hypoglossal nerve stimulator. These examinations therefore do not involve any additional risk or discomfort.

Within this trial, additional measurements for collapsibility will be performed during a standard sleep endoscopy. There are few additional risks associated with the additional measurements (mask, sensors on the head, and straps around the chest and abdomen).

6.2. Will my participation to the trial have an impact on my daily activities?

There is no impact on your daily activities from the trial.

7. What If something goes wrong within the trial?

Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the trial. The sponsor has taken an appropriate insurance (a so called “NO FAULT INSURANCE”) for this liability (Ref. 1). A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the trial, you must inform your investigator or trial staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the trial is possible, he/she will inform the trial sponsor. The sponsor will then immediately initiate the declaration procedure to its insurance company. If the

company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the trial. The insurance does not cover the natural progression of your disease/condition or the known side effects of the treatment you would have received without taking part to the trial (*that is* your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. You will find the contact details on the front page of this form.

8. What if other treatment options or new information on the trial become available during the course of the trial?

During the course of the trial, important new information might become available, possibly affecting your decision to (further) participate. For example other treatments for your obstructive sleep apnea or important new information on the treatment may become available. It is the duty of the investigator to discuss this new information with you and to give you the opportunity to re-consider your participation in the trial.

If you decide to stop taking part in the trial or if you are no longer able to participate, your investigator will see to it that you continue to receive the best possible medical care.

9. Can my participation in the trial end prematurely?

As explained in detail below, your trial participation may end prematurely when

- you decide to withdraw your consent,
- the investigator decides to end your trial participation, or
- other entities interrupt or end the trial.

In any case, if your trial participation ends prematurely, the investigator will discuss your future medical care with you. The sponsor can continue to retain and use any data that have already been collected before the end of your participation. This is to avoid skewing / biasing results of the trial (as described in I. § 12.4., page 13).

If you experience a side effect at the moment of stopping the trial procedure, the investigator may contact you in the future to see if it has resolved or not after the end of the trial participation.

If you experience a new side effect after the end of your trial participation you may contact the investigator to ask for a follow-up.

9.1. You decide to withdraw your consent

You are entitled to withdraw your consent for any reason, at any time, without having to justify your decision. However, for your safety, you should inform the investigator of your decision. Although it is not mandatory, it may be useful for the investigator and for the sponsor to know the reason of your decision (for example side effects, frequency of clinical visits,…).

If you withdraw your consent, this means you decide to stop

- Undergoing the examination if it is not necessary as part of your standard treatment, and
- all trial-related visits and examinations.

Please discuss with your investigator to evaluate the practical modalities of your withdrawal (in light of your situation), including any follow up-visits or procedures.

In any case, no new data will be sent to the sponsor.

9.2. The investigator decides to end your trial participation

The investigator may end your trial participation because

- you become pregnant during the trial,
- it is better for your health,
- he/she determines that you are not following the instructions given to participants, or
- any other reason that will be explained.

If that happens, the study staff will explain why and ensure appropriate follow-up.

9.3. Other entities may interrupt or end the trial

The sponsor and the competent Belgian health authorities may interrupt or end the trial because

- because the trial causes more (serious) side effects than expected, or
- for another reason that will be explained by the relevant authority.

10. Which treatment will I get after my participation in the trial?

There is no treatment associated with the study itself, as you already have a hypoglossal nerve stimulator.

After participating in this study, you will be able to continue using the hypoglossal nerve stimulator. All future costs will be covered by your health insurance fund (Belgian social security), as this medical device is already available on the Belgian market and has been fitted as part of your standard care.

11. Will my participation in the trial involve extra costs for me?

11.1. Examinations and treatments paid by the sponsor

As described in section 4, the examinations and treatments that are specific to the trial will not be charged to you. The treatments and examinations that are part of your

standard care will either be billed to you or reimbursed by your health insurance (Belgian social security).

In other words, the sponsor will reimburse the hospital or trial center for:

- The time spent on the trial by the investigator and the trial staff.
- The visits/appointments and all planned examinations that are specific to the trial.

In the following text, you will find which procedures are trial-specific and therefore will not be charged to you as a participant. The other treatments and examinations, which belong to the standard care for your condition, will be billed to you or your health insurance (Belgian social security).

- Additional measurements during the sleep endoscopy: EEG (electrodes on the head), EOG (electrodes around the eyes), chin EMG (electrode on the chin), respiratory effort (two belts around the chest and abdomen), breathing pattern (mask).

11.2. Other expenses paid by the sponsor

You will not receive any compensation for participating in the trial.

12. Which data are collected about me during the trial and what will happen with them?

12.1. Which data are collected and processed during the trial?

The collected and processed personal data concern information about your health and medical condition. This includes your medical history, some of your background information (for example your age, sex, and ethnic origin) and the results of examinations required by the trial.

12.2. How will the investigator treat my personal data?

The investigator is bound by professional secrecy about the data collected.

This means that he/she will never reveal your identity, including in a scientific publication or a lecture and that he/she will encode your data (*that is* by replacing your identity by an identification code in the trial) before sending them to the sponsor.

Therefore, the investigator and the trial staff under the responsibility of the investigator, will be the only ones able to establish a link between your identity and the data transmitted during the trial, with the exceptions listed under section 12.6.

The data transmitted to the sponsor will not allow the sponsor to identify you.

12.3. What will happen to information about me collected during the trial?

Your participation in the trial means that your personal data

- are collected by the investigator, and
- are used in an encoded form by the trial sponsor.

The investigator and the sponsor can only use the encoded personal data for research purposes in connection with scientific publications within the context of the trial that you participate in, or for a broader use of the encoded data if described below.

In addition, the sponsor may provide access to the encoded data to external researchers (that are not involved in this trial). In the event an external researcher wants to use the data in a project not yet described in this document, this project will have to be approved by an Ethics Committee. If your encoded trial data are sold, you will not benefit from this.

12.4. How will my data be handled?

Your trial data will be processed in accordance with the General Data Protection Regulation (GDPR, Ref. 2) and the Belgian law on data protection of 30th July 2018 (Ref. 3). The sponsor is responsible for this processing.

Processing your personal data in this trial is allowed because we are conducting scientific research and you have given your **consent.**

12.5. Do I have access to my data collected and processed during the trial and can I rectify them?

You are entitled to ask the investigator what data are being collected about you and how those data will be used in connection with the trial.

You have the right:

- to inspect and access these data
- to have all your data erased
- to ask for correction if they are incorrect,
- to restrict the processing of your data.
- to object to the processing of your personal data
- to withdraw your consent for the processing of personal data. However personal data collected before withdrawal will be kept to avoid skewing of results in the trial.

12.6. Who, other than the Investigator and his staff, has access to my personal data?

To verify the quality of the trial, it is possible that your personal **un**coded data or information in your medical records relevant for the trial, will be examined by people outside the trial staff but under the responsibility of the investigator. These persons must be subject to professional secrecy or a confidentiality agreement. The following might be considered:

- the personnel designated by the sponsor of the trial (MONITORS and AUDITORS), and people or organisations providing services for or collaborating with the sponsor. They will however never transfer your name and contact details to the sponsor.
- inspectors of competent health authorities worldwide
- an independent audit group

- people designated by the Ethics Committee

For the needs of the trial, the encoded trial data may be sent to other EU and non-EU countries and may be reviewed by

- personnel (other than the inspectors) of competent health authorities of Belgium (Federal agency for medicines and health products, FAMHP) and other EU and non-EU countries,
- the evaluating Belgian Ethics Committee(s),
- external researchers,
- the sponsor of the trial, personnel designated by the sponsor, and people or organizations providing services for or collaborating with the sponsor, and/or
- group companies of the sponsor in Belgium, and in other EU and non-EU countries.

The European regulation and the Belgian legislation on data protection have requirements for transferring data to non-EU countries. The sponsor must ensure equivalent guarantees regarding personal data protection standards before transferring the encoded data to non-EU countries. If for this purpose, there is a data protection agreement, a copy of this agreement may be obtained via the investigator. You can always contact your investigator to obtain more information about any such transfers.

12.7. What will happen to the results of the trial?

After trial closure, a description and the results of this clinical trial will be published in specialized medical journals. A copy of the scientific publication can be obtained from the investigator or the trial staff.

A description of the trial will also be available on https://www.clinicaltrialsregister.eu/ and/or https://www.Clinicaltrials.gov. You can search these websites at any time using the trial number given on the front page of the informed consent form. The websites will include a summary of the results within 1 year after the end of the trial (Ref. 4).

These websites or publications will not include information that can identify you.

12.8. Will my data be used for other purposes than for the trial in which I take part?

The results of the trial will be used to answer the scientific questions of the trial. In addition, the sponsor would like to use your data obtained from this trial, in connection with other research and development activities (and the associated scientific publications). These may be passed on to external researchers. If your encrypted data is passed on, whether or not for a fee, you will not be compensated for this. Your data may be passed on for research purposes.

These activities may concern

- the way the hypoglossal nerve stimulator and devices of the same group work,
- the disease/condition for which the hypoglossal nerve stimulator is evaluated in this trial or

- other diseases and health problems which could benefit from hypoglossal nerve stimulation, or from related diagnostic tests.

Any additional research outside of the trial, must be approved by a Belgian recognized Ethics Committee.

At the end of this form you agree or disagree to the use of your trial data for other purposes by ticking the appropriate check-box in Chapter II, page 16.

12.9. How long will my data be kept?

After the end of the trial your encoded data will be retained for at least 25 years (Ref. 5) to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

13. Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by

- The Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and
- An independent Belgian Ethics Committee

It is the task of the competent health authorities and the Ethics Committees to protect people who take part in a trial. The health authorities will ensure that the trial is conducted in accordance with the applicable legislation.

You should not under any circumstances take their approval as an incentive to take part in the trial.

14. What happens in case of incidental findings?

If by chance and in addition to the trial objectives a result is discovered during the trial that may be important to your health or the health of your blood relatives (called “incidental findings”), the sponsor will inform the investigator. With your consent the investigator will notify you and your treating physician about your results and potential consequences. If necessary, the investigator and/or the treating physician will advise you on the next steps.

You can let the researcher know whether or not you agree to be informed about meaningful information discovered about your health by ticking the relevant checkbox in Chapter II, page 16. The researcher/your treating physician will inform you about this information in any case where not being informed may cause serious harm to your health or that of third parties.

CHAPTER II - INFORMED CONSENT

Assessment of the effect of hypoglossal nerve stimulation (HNS) therapy on upper airway collapsibility during drug-induced sleep endoscopy

PARTICIPANT

PREREQUISITES FOR YOUR PARTICIPATION IN THE TRIAL

- I declare that I have read this form and understood its information.
- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration and consequences, possible risks and discomforts, the precautions that I must take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- I understand that my participation in this trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially as described in Chapter I, §12.2.
- I understand that representatives of the sponsor, the ethics committee, and competent health authorities have access to my medical record if authorised to do so (as described in Chapter I, § 12.6).
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease.
- I am aware that my treating physician(s) being informed of my participation in this trial.
- If I take part in another interventional trial, I must inform the investigator or trial team about this. I agree not to take part in any other interventional trial (e.g. with a study drug, medical device, experimental surgical technique) at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator's and trial staff's instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- I certify that all the information I have given about my medical history is correct, to the best of my knowledge. I understand that it may be harmful to me if I do not inform the investigator of possible reasons why I could not participate in the study.

OPTIONAL CONSENTS WHICH ARE NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS TRIAL.

DATA OBTAINED FROM THIS TRIAL

1. As specified in Chapter I, § 12.8, page 14, the sponsor would like to be able to use your data obtained from this trial for other research and development activities (and the associated scientific publications) on the condition that such research purposes have been approved by a Belgian recognized Ethics Committee.

   Do you agree with the use of your data obtained in this trial for other research purposes?

   (Tick as appropriate)

☐ **I agree**	☐ **I do not agree**

MEANINGFUL INFORMATION

2. As specified in Chapter I, § 14, page 15, it may occur that meaningful information is discovered that may be important for your health or that of third parties.

   If this were to occur, would you like the researcher/your treating physician to inform you of this result?

   (Tick as appropriate)

☐ **No, I do not want to be informed**	☐ **Yes, I wish to be informed**

I consent to take part in the trial, with the above restrictions and I have received a signed and dated copy of all pages of this document.

Participant's surname and first name:

Date (DD/MMM/YYYY):

Participant's signature:

INVESTIGATOR

I, the undersigned investigator, confirm that

- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- I operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law (Ref. 6).

Investigator’s, Surname and first name:

Date (DD/MMM/YYYY):

Investigator’s signature:

CHAPTER II - INFORMED CONSENT

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PARTICIPANT

PREREQUISITES FOR YOUR PARTICIPATION IN THE TRIAL

- I declare that I have read this form and understood its information.
- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration and consequences, possible risks and discomforts, the precautions that I must take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- I understand that my participation in this trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially as described in Chapter I, §12.2.
- I understand that representatives of the sponsor, the ethics committee, and competent health authorities have access to my medical record if authorised to do so (as described in Chapter I, § 12.6).
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease.
- I am aware that my treating physician(s) being informed of my participation in this trial.
- If I take part in another interventional trial, I must inform the investigator or trial team about this. I agree not to take part in any other interventional trial (e.g. with a study drug, medical device, experimental surgical technique) at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator's and trial staff's instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- I certify that all the information I have given about my medical history is correct, to the best of my knowledge. I understand that it may be harmful to me if I do not inform the investigator of possible reasons why I could not participate in the study.

OPTIONAL CONSENTS WHICH ARE NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS TRIAL.

DATA OBTAINED FROM THIS TRIAL

3. As specified in Chapter I, § 12.8, page 14, the sponsor would like to be able to use your data obtained from this trial for other research and development activities (and the associated scientific publications) on the condition that such research purposes have been approved by a Belgian recognized Ethics Committee.

   Do you agree with the use of your data obtained in this trial for other research purposes?

   (Tick as appropriate)

☐ **I agree**	☐ **I do not agree**

MEANINGFUL INFORMATION

4. As specified in Chapter I, § 14, page 15, it may occur that meaningful information is discovered that may be important for your health or that of third parties.

   If this were to occur, would you like the researcher/your treating physician to inform you of this result?

   (Tick as appropriate)

☐ **No, I do not want to be informed**	☐ **Yes, I wish to be informed**

I consent to take part in the trial, with the above restrictions and I have received a signed and dated copy of all pages of this document.

Participant's surname and first name:

Date (DD/MMM/YYYY):

Participant's signature:

INVESTIGATOR

I, the undersigned investigator, confirm that

- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law (Ref. 7).

Investigator's, Surname and first name:

Date (DD/MMM/YYYY):

Investigator's signature:

GLOSSARY

DPA: The Data Protection Authority ensures that personal data are handled with care and thoroughly protected, and that your future privacy also remains guaranteed.

FAMHP: Federal agency for medicines and health products

HNS: Hypoglossal nerve stimulation, a treatment in which a device is implanted that stimulates the hypoglossal nerve at night to keep the airway open in patients with obstructive sleep apnea.

NO FAULT INSURANCE:

The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR

Both the monitor and auditor work for the sponsor.
The monitor takes care of a continuous quality check during the course of a trial. The auditor performs a quality check after the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according to the applicable rules.

REFERENCES

[1] This is in accordance with Article 29 of the Belgian Law of 7 May 2004 related to experiments on humans.

[2] General Data Protection Regulation No 2016/679 of the European Parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

[3] The Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

[4] In accordance with section 4.3. of the Commission Guideline: Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 - (2012/C 302/03). [From the moment the Clinical trial regulation enters into force : In accordance with article 37 of the Clinical trial regulation No 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC; sponsor have to provide summary results of clinical trials in a format understandable to laypersons.]

[5] In accordance with article 58 of the Clinical trial regulation No 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[6] Belgian Law of 7 May 2004 related to experiments on humans, and the applicable royal decrees.

[7] Belgian Law of 7 May 2004 related to experiments on humans, and the applicable royal decrees.