ótologie
tinnitus care

Patient Information Leaflet

Investigation title: Tinnitus Patient Registry at Ótologie Tinnitus Care (Ótologie)

Sponsor:

Neuromod Devices Ltd

The Digital Hub, Unit J, Digital Court, Rainsford Street, Dublin 8, D08

R2YP, Ireland

Promotor(s):

Name PI: Anita Sayers

Name site: Ótologie Tinnitus Care, Hermitage Medical Clinic

Tel: +353(1) 253 1448

Investigator(s)/Coordinating Investigator:

Name investigator: Helen MacMahon

Name site: Ótologie Tinnitus Care, Hermitage Medical Clinic

Tel: +353(1) 253 1448

Contact person for information:

Name: Anita Sayers or Helen MacMahon

Site: Ótologie Tinnitus Care, Hermitage Medical Clinic

Tel + e-mail: 01 253 1448 and **appointments@otologie.com**

Contact in case of a medical emergency:

During clinic hours: +353(1) 253 1448

Outside clinic hours: Please contact your GP, A&E or Doctor on Call

Medical Ethics Committee

National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD)

National Office for Research Ethics Committees

Grattan House

ótologie
tinnitus care

67-72 Lower Mount Street

Dublin 2

D02 H638

Tel: +353 (1) 234 5000

Email: nationaloffice@nrec.ie

Dear Patient,

You are being invited to participate voluntarily in a clinical research investigation supported by Neuromod Devices Ltd (the Sponsor), the manufacturer of the *Lenire*® device, which is a CE-marked medical device intended to alleviate the symptoms of tinnitus. Ótologie Tinnitus Care, where your tinnitus care is provided, is a fully owned subsidiary of Neuromod Devices Ltd. As the investigation follows standard of care at the clinic, no additional funding is provided by the Sponsor outside of that already available to the clinic, and is to be carried out by Anita Sayers, at Ótologie Tinnitus Care (Ótologie), Hermitage Medical Clinic, Dublin, Ireland. The investigators will follow the usual practice with the tinnitus treatments provided by Ótologie and you will not be required to complete any additional questionnaires or assessments.

Before consenting to participate in this investigation, it is important that you read this form. This will explain why the investigation is being conducted and what your participation will involve. You should clearly understand the risks and benefits of taking part in this investigation so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Please take time to read the following information carefully and feel free to discuss it with your General Practitioner, and friends and family, if you so wish. You will have an opportunity to discuss any questions you may have with the clinic team before committing to participate in the investigation. You should take time to decide whether or not you wish to take part in this investigation.

You don't have to take part in this investigation. If you decide not to take part it won't affect your future medical care and no attempt will be made to access your personal data.

You can change your mind about taking part in the investigation any time you like. Even if the investigation has started, you can still leave the investigation. You don't have to give us a reason. If you do leave the investigation, rest assured it won't affect the quality of treatment you get in the future. However, we ask that you advise a member of the clinic team and attend an early discontinuation visit if you do decide to withdraw from the investigation.

Investigation-specific information

This investigation was approved on *20th January 2022* by the independent National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD).

Aim and description of the investigation

This is a scientific investigation in which approximately 420 people per year are expected to is participate. You have been invited to participate in this investigation because you have tinnitus and are attending or plan to attend the Ótologie Tinnitus Care for treatment.

This is a patient registry which means that the investigation aims to assess the effectiveness of tinnitus treatments provided at Ótologie through the analysis of real-world data, collected as part of standard of care.

The medical devices available for treatment include the *Lenire* device and hearing aids. Both of these devices are approved for use in patients in Europe. As such, this investigation is a Post Market Clinical Follow-Up investigation. This means that the devices will be used as in standard practice for treating tinnitus. As this is a registry, there will be no additional questionnaires or assessments for patients participating in the investigation. All of the assessments are routinely carried out as standard of care. There are no experimental procedures or assessments as part of this investigation. The purpose of the investigation is to collect data on the treatments provided at Ótologie in order to gain a better understanding of the treatment of tinnitus in order to improve tinnitus treatments and treatment pathways

All patients that are over 18 and are eligible for tinnitus treatment at Ótologie will be invited to participate in the registry. A member of the Ótologie team may have already discussed the registry with you and you will have the opportunity to take time to read this information leaflet, ask any questions and discuss the investigation in further detail, if you wish to do so. If you are interested in participating, you will be asked to sign an Informed Consent Form (attached to this information leaflet).

As part of routine standard of care at Ótologie, the investigator will ask/perform and collect data using questionnaires and assessments. If choosing to participate in the investigation, you are agreeing to share the data and outcomes of these assessments with the investigation team for analysis. If you are undergoing tinnitus therapy, none of the private session information will part of the investigation. Data from the following questionnaires and assessments will be collected as part of the registry:

Hearing assessment (test carried out to determine your level of hearing and check for abnormalities of the ear).

Tinnitus assessment; involves completion of one tinnitus questionnaire (Tinnitus Handicap Inventory), questions relating to your tinnitus history and current tinnitus status (sound type/location/nature/severity).

Questions related to your tinnitus, sleep, general well-being and treatment (Clinical Global Impression Scale and Visual Analog Scale).

Medical and medication history

Demographic data will be collected to gather baseline characteristics of patients. Demographic information includes gender, age, race, ethnicity, employment status and current/previous member of military status.

Participation in the investigation may only take place after you have signed the Informed Consent Form agreeing to participate.

Tinnitus Treatments

Ótologie Tinnitus Care currently offer the following three types of tinnitus treatment:

Neuromodulation with the *Lenire* device

The *Lenire* device is a CE marked medical device intended to reduce the symptoms of tinnitus. The *Lenire* device consists of a handheld controller which is about the size/weight of a mobile phone and a Tonguetip® (mouth-piece) device. It is designed to be used with the set of headphones supplied

in the comfort of your own home. The device provides stimulation in the form of audio/sound patterns played through the set of headphones. At the same time tactile patterns consisting of small electrical pulses will be delivered to the tip of the tongue via the Tonguetip that sits on the top surface of your tongue. The stimulation from the Tonguetip is not uncomfortable and you will have the ability to adjust the intensity of the stimulation during treatment. A charger is included that can be used to charge both the controller and the headphones. The investigator will explain fully how and when to use the device at your fitting visit.

Amplification and/or masking with hearing aids

It is well documented in research that tinnitus is related to hearing deficit and occurs more frequently in the hearing-impaired population. Research suggests that tinnitus in the hearing-impaired population may be caused by loss of input to the auditory nerve. When hearing aids amplify sound it provides stimulation to the auditory nerve and increases overall auditory input. In addition to this, with an increase in overall amplification the tinnitus itself may be less noticeable. This may be particularly beneficial to those who experience tinnitus most in quiet environments. If hearing aids are recommended to treat your tinnitus symptoms, you will be provided with information about hearing aids at the initial assessment.

Tinnitus Therapy, which is provided by a psychotherapist and includes cognitive behavioural therapy (CBT)

Tinnitus Therapy is a form of psychotherapy which aims to change a patient's perception of their tinnitus and minimise its impact on their life. Tinnitus Therapy provides a supportive and non-judgemental environment so the patient and therapist can discuss and develop an understanding of the patient's tinnitus, as well as techniques to change their thought processes, behaviours, and feelings related to it. The Ótologie team recognise that each patient and their experience of tinnitus is different. Tinnitus is a complex condition which affects the emotional, attentional, and behavioural centres of the brain. Therefore each treatment plan for Tinnitus Therapy is tailored to the patient, integrating different therapeutic approaches from cognitive behavioural therapy, humanistic therapy, and more.

These treatments are offered after an audiological assessment, and you will be provided with further information about the treatment which is recommended to treat your tinnitus. You may undergo one or more of these treatments. The data obtained through the tinnitus registry could provide valuable evidence towards continuing to understand the effectiveness of hearing aids, *Lenire* and tinnitus therapy in the treatment and management of tinnitus.

While there is no placebo treatment in this investigation, your response to the treatment may vary depending on your tinnitus symptoms.

Duration of the investigation

It is planned that the registry will collect data on tinnitus treatment for a period of 10 years. You will not be required to do anything additional to standard of care treatments during this period as the registry relates only to the collection of data.

What do I have to do?

In order to participate in this investigation, you must agree to allow the investigators to access your data for the duration of your treatment at Ótologie Tinnitus Care and share this data in a pseudo-anonymised format with the Sponsor for analysis purposes.

Benefits and disadvantages

We cannot guarantee that if you agree to participate in this clinical investigation, you will directly benefit from your participation in this investigation. However it will add to the scientific knowledge in the area of tinnitus research. The results will not be shared with individual patients. You will not incur any additional costs for this investigation. In relation to time commitment, participation in the registry will not take any additional time as there are no additional questionnaires or assessments. The results of this clinical investigation may contribute to the optimisation of the treatment which could benefit you and other tinnitus sufferers in the future.

The risks of participating in the investigation are limited, as the tinnitus treatments are available commercially, so safety and performance outcomes are therefore considered to be acceptable.

Risks to consider when participating in the clinical investigation:

Collection of Personal Data may lead to loss of confidentiality, even in which protocols are implemented to secure and protect this Personal Data, it comes with the risk that security measures can be breached, or Personal Data is unintentionally released or accessed.

What happens if something goes wrong?

We do not foresee any significant risks to participants in this investigation. The *Lenire* and hearing aid devices are CE-marked and approved for sale in Europe. Any risks or warnings for the treatment pathway that is recommended for you will be detailed in the IFU and/or by your Audiologist/Therapist at Ótologie Tinnitus Care before you begin any treatment.

Nevertheless, during research things can occasionally go wrong and unanticipated risks may occur. If you have serious concerns, you should stop using the device immediately and contact the Principal Investigator Anita Sayers, Ótologie Tinnitus Care, Hermitage Medical Clinic, Tel: +353(1) 253 1448.

Outside of clinic hours, contact **appointments@otologie.com** or in the case of an emergency please contact Doctor on Call, A&E or the emergency services (call 112 or 999). You will be under the care of Anita Sayers and they and their team will take care of you. The team will look into what went wrong and make sure that you are treated properly and that there is no risk to other participants. You may be referred to your primary care or GP for medical treatment according to the usual standards. We will not contact your GP or inform them of your participation in the registry without your consent to do so.

What are the alternatives for treatment?

There are a number of other treatments/therapies available for your condition that your Consultant, Audiologist or GP can discuss with you.

What happens if new information becomes available?

Should any new information become available during the course of the investigation that may affect your willingness to participate, you will be informed of this in writing. If you decide to withdraw from the investigation, your care at Ótologie will not be affected.

What happens when the investigation stops?

If the investigation is terminated or ends during a period where you are still receiving care at Ótologie, your treatment will not be affected. The Sponsor can terminate or prematurely stop the investigation at any time during the investigation period for any reason.

What happens if the study is terminated earlier than planned?

This is a post approval investigation of a CE marked investigational device and early termination is not anticipated. Adequate resources and planning have been put in place to ensure successful completion of the investigation; however, early termination may occur due to unforeseen circumstances such as unanticipated lockdowns that make continuing the investigation extremely difficult. The Sponsor, Research Ethics Committee and governing bodies/Health Authorities reserves the right to terminate the investigation at any time without giving reason. In such cases, the Sponsor shall notify the relevant Principal Investigators and Ethics Committees of its decision and rationale in writing.

Occasionally, clinical investigations are stopped earlier than planned, for example if there are unexpected or unacceptable risks to the participants, operational difficulties, or unforeseen occurrences. If the investigation is stopped early you may be contacted by a member of the research team who will explain the reasons for the investigation stopping. In some cases the investigation may resume again if resolution to the issue is found. All participants will be treated as per standard of care at the investigation site after the investigation is terminated.

Early termination may occur if you (the participant) wants to stop participating in the study. As per section below ‘What if I want to withdraw from the investigation?’ you can withdraw from the investigation at any time without an explanation as to why you want to stop. You should report this to the investigator as soon as possible. The investigator may also withdraw you from the investigation at any time if they believe it is in your best interests. You will be able to discuss further treatment options with your GP or Consultant.

What if I want to withdraw from the investigation?

You are completely free to discontinue participation in the investigation at any point. If you withdraw, your regular medical care will not change. You do not have to provide a justification for your withdrawal. If you are thinking about leaving, please tell the research team. Any information collected about you up until your withdrawal cannot be removed. This information is valuable to the research team and must remain available to them.

If you wish to withdraw, please contact the investigation team using the contact information provided on the first page of this information leaflet and they will ensure that your withdrawal is updated on the investigation database and that your future data is not included in the registry.

Your withdrawal from the investigation will not affect your future medical care in any way.

The investigation team or the Sponsor may withdraw you from the investigation for any reason without your consent. Similarly, your primary care provider, GP or the principal investigator of the study may withdraw you from the investigation at any time, without your consent. Possible reasons for removal include:

It is in your best interest

You have a side effect that requires stopping the research

The research is cancelled by the regulator or the sponsor

If you are removed from this research, the reasons for removal will be explained to you, and any further clinical care will be discussed.

General information about participating in an investigation

Voluntary participation

If you consent to participate in the Registry, a copy of this information leaflet will be provided to you and you will be asked to sign the attached informed consent form.

Your participation in this investigation is entirely voluntary, and you have the right to refuse to participate.

You have the right to withdraw your participation in this investigation at any time, even after you have signed the informed consent form. You do not have to give any reason for doing so. Withdrawing your consent will not have any negative effect or loss of benefits.

Your decision to participate or not in this investigation or to stop your participation will not have any influence on your further treatment or your relationship with the clinic.

Your participation in the investigation can be stopped at any time, without your permission, by the investigator(s), the Ethics Committee, or the Sponsor. Possible reasons for such a decision include:

Your further participation seems hazardous for you.

It was ascertained during the investigation that you do not or no longer fulfil the criteria for participation.

The Sponsor, Research Ethics Committee and governing bodies/health authorities reserves the right to terminate the investigation at any time without giving reason. In such cases, the Sponsor shall notify the relevant Principal Investigators and Ethics Committees of its decision. All patients will be treated as per standard of care at the investigation site after the investigation is terminated.

Liability and insurance

The Sponsor of this investigation has taken out appropriate levels of insurance to cover unforeseen circumstances as part of its normal clinical practice. If you suffer harm as a result of your participation in this investigation, you or your beneficiaries will be compensated for that harm by the investigation sponsor, in line with Irish legislation.

Cost and compensation

You will not incur any additional costs for this investigation. All costs from your participation in the investigation are charged to the investigator or the Sponsor. Costs that are not associated with the investigation but that form part of your treatment are charged to you and your healthcare insurer.

Protection of your personal privacy

Your identity and your participation in this investigation will be treated with strict confidentiality. You will never be identified by name or otherwise in files, results or publications linked to the investigation.

To guarantee your privacy regarding the storage and processing of the data in the context of this investigation, your data will be pseudonymised. This means that your surname, first name, full date of birth and town/city of residence will be replaced by a code. All further processing uses the pseudonymised data. The link between the code and you is kept on file at the Ótologie Tinnitus Care. This link is only used in your best interests to trace certain information back to you.

Protection of your personal data

If you consent to participate in this investigation, you are consenting to the use of your personal data that is collected in the context of the investigation. The data will be used for the evaluation of the investigation and may be used in the future in related studies (by Sponsor or research collaborators) if you consent to this. The data may be submitted to global health authorities/notified bodies for registration purposes. EU inspectors are entitled to directly access the medical records (including applicable electronic systems) of clinical investigation participants for investigatory purposes. In addition, Members of health authorities, members of research ethics committees, sponsors, or sponsor representatives, or other persons entitled or required by law to do so may access your medical records. This is done in order to verify the accuracy of collected data.

Data may also be used in publications, presentations, or other reporting outlets about the medical device; however, your identity will not be revealed in any compilations, investigation reports or publications. Prior to any publications the investigation shall be registered in a publicly accessible database. The lawful basis for the processing of your Personal Data for the purposes of the clinical investigation is legitimate interests under Article 6(1)(f) of GDPR, and for special category data public interest in the area of public health based on Union or Member State law under Article 9(2)(j) of GDPR.

You have the right to ask the investigator about what data is being collected about you in the context of the investigation and what its purpose is. You can withdraw this consent to collect and process your data at any time. If your participation in the investigation is terminated prematurely, your original consent allows use of the data collected about you during the period that you were included in the investigation. You can make this request to the clinic team at Ótologie Tinnitus Care or email anita.sayers@otologie.com.

The investigator maintains all clinical investigation records for the minimum time required under Irish law, Medical Device Regulations (MDR) or for the minimum retention period indicated by the Sponsor, whichever is the longer timeframe. When the minimum retention period has elapsed, investigation documentation will not be destroyed without permission from the Sponsor. All investigation documentation will be kept by the Sponsor for a minimum of 10 years from the end of the investigation or at least 10 years after the last device has been placed on the market, whichever is longest, as required by the Medical Device Regulations .

Personally identifiable data (which refers to e.g. your name, date of birth and contact details) will only be stored in the Ótologie Tinnitus Care clinic and not transferred to the Sponsor. Your Personal Data may be transferred outside of the EEA to other regulatory bodies. The investigation sponsor Neuromod Devices Limited shall act as data controller for your data. Technical and organisational measures are in place to protect the confidentiality of data and to ensure the same standards of data protection to process your data in accordance with the European General Data Protection Regulation (GDPR), MDR and with the Irish legislation on the protection of natural persons with regard to the processing of personal data. The sponsor ensures these measures are upheld for any data processed outside of the EEA.

The safeguards in place with regard to the transfer of your Personal Data outside of the EEA to third parties shall include (but shall not be limited to) the entry by the Sponsor and its designees into appropriate contracts with all transferees of such data.

If you feel that your rights concerning your personal data are not being properly respected, you can also turn to the data protection officer, who will take the necessary steps if needed.

Data Controller and Data Processor: Neuromod Devices Ltd

Data Controller Contact Details: info@neuromoddevices.com/gdpr@neuromoddevices.com

Data Protection Officer (DPO): Clare Bryan (Sponsor DPO)

Data Protection Officer Contact Details: cbryan@grcilaw.com

You also have the right to submit a complaint to the Irish Data Protection Commission.

More information is available at **https://www.dataprotection.ie**.

Future use of data

By signing this Informed Consent Form, you are giving permission to use your Personal Data for the current research detailed. There is an additional check box on the Informed Consent Form where additional voluntary consent is being sought to store the data collected during this investigation for possible future unnamed research studies unrelated to the current investigation but in the same area of research (i.e., tinnitus and hearing research only) for non-commercial purposes. This could be research initiated by the Sponsor and your data would not be shared to additional third parties unless additional consent is obtained. Only the Ótologie Tinnitus Care clinic and investigation team will have access to your Personally Identifiable Data (i.e. name and contact details). Future research will be approved by a Research Ethics Committee and use of your data will be in compliance with Data Protection Regulations and all applicable legislation.

This research would be limited in all cases to the area of tinnitus and hearing. This may involve using the baseline data in epidemiology studies of tinnitus, aggregating the data in combination with other investigations as part of post market follow up studies/regulatory submissions and further responder analysis.

You can withdraw your consent for future uses at any time by contacting the clinic team using the contact details provided on the first page of this Patient Information Leaflet.

Further information or questions

You have the right to ask additional questions at any time about the content, purpose, or course of the investigation, about potential and/or known benefits and disadvantages this investigation may have for you, etc. You can turn to the principal investigator, Anita Sayers, for this at +353(1) 253 1448 and anita.sayers@otologie.com or appointments@otologie.com..

For medical or technical concerns or queries regarding your appointments please contact the investigation's coordinator between the hours of 9am – 5pm on Monday to Friday at 353(1) 253 1448. For medical concerns outside of the routine office hours, please contact Ótologie Tinnitus Care at anita.sayers@otologie.com or appointments@otologie.com and the team will respond as soon as possible. In the case of an emergency please contact Doctor on Call, A&E or the emergency services (call 112 or 999).

We hope that this document provides you with sufficient information about the investigation.