Official Title: **Randomised, Double-Blind, Crossover Clinical Trial: Deep Brain Stimulation of the Posterior Subthalamic Area versus the Ventral Intermediate Nucleus of the Thalamus in Refractory Essential Tremor**

Document Type: INFORMED CONSENT FORM

Version Date: 7 October 2019

INFORMED CONSENT FORM

Study Title

Randomised, Double-Blind, Crossover Clinical Trial: Deep Brain Stimulation of the Posterior Subthalamic Area versus the Ventral Intermediate Nucleus of the Thalamus in Refractory Essential Tremor

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Study Site

University Hospital Virgen de las Nieves, Granada, Spain

Invitation to Participate

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being conducted and what it will involve for you.

Please take time to read the following information carefully. You may discuss it with family, friends, or your general practitioner if you wish. Ask us if anything is unclear or if you would like further information.

What is the purpose of the study?

Essential tremor typically presents as an action, postural or kinetic tremor, usually bilateral and relatively symmetrical, most commonly affecting the hands and forearms, and less frequently the legs, trunk, head, and voice.

You have been selected as a candidate for Deep Brain Stimulation (DBS) to treat your tremor, which has not responded adequately to conventional treatments.

Currently, the standard target for DBS is the Ventral Intermediate Nucleus (VIM) of the thalamus. However, this approach may be associated with reduced effectiveness over time (tolerance) and certain side effects, such as gait disturbances and speech difficulties, which may affect quality of life.

The purpose of this study is to evaluate whether stimulation of a second target—the Posterior Subthalamic Area (PSA), located below the VIM—provides similar or improved tremor control with fewer side effects and reduced battery consumption.

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Why have I been invited?

You have been invited because you meet the criteria for DBS treatment and are considered an appropriate candidate based on your clinical condition.

Do I have to take part?

No. Participation is entirely voluntary.

If you decide to take part, you will be given a copy of this information sheet and asked to sign this consent form. You are free to withdraw at any time, without giving a reason, and this will not affect your medical care or your relationship with your doctors.

What will happen to me if I take part?

If you agree to participate, you will undergo the standard DBS procedure as explained in the specific consent form for DBS at this centre.

Using the same electrode trajectory, it will be possible to stimulate either:

- The VIM (upper contacts), or
- The PSA (lower contacts)

After surgery, you will be randomly assigned to one of the following sequences:

- VIM stimulation for 3 months followed by PSA stimulation for 3 months, or
- PSA stimulation for 3 months followed by VIM stimulation for 3 months

After each stimulation period, neurological and neuropsychological assessments will be performed.

Between both stimulation phases, there will be a **one-week washout period**, during which:

- The stimulator will be switched off
- Your tremor will return and may temporarily worsen
- You will not be allowed to take tremor medication

At 12 months after surgery, a final evaluation will be performed.

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Important note

During the 6-month study period, all medication for tremor will be discontinued.

What will I have to do?

In addition to standard follow-up visits, you will attend:

- Neurological and neuropsychological assessments at 3, 6, and 12 months
- An additional programming visit at 3 months (after washout period)

These visits will take place at the Neurology Department, Functional Testing Unit, University Hospital Virgen de las Nieves.

What are the possible benefits of taking part?

You and future patients may benefit from improved understanding of DBS treatment, potentially leading to:

- Better tremor control
- Fewer side effects
- Reduced need for battery replacements

At the end of the study, your device will be programmed using the settings that provide you with the best balance between benefit and side effects.

What are the possible risks of taking part?

In addition to the risks explained in the standard DBS consent form, potential side effects include:

- Gait disturbance, including ataxia
- Speech disorders (e.g. dysarthria, hypophonia)
- Sensory disturbances (e.g. paraesthesia, altered taste)
- Less frequently: swallowing difficulties, hypersalivation, mood changes (including depression), or cognitive changes

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During one of the study periods, you may receive stimulation that is less effective or associated with more side effects.

During the washout period, your tremor will return and you will not be able to take medication.

Additional risks may exist depending on your individual medical condition.

Confidentiality

Your participation will remain confidential at all times.

All data will be handled in accordance with applicable data protection laws, including the **General Data Protection Regulation (GDPR)**.

- Your data will be coded and anonymised
- Only authorised members of the research team will have access
- Data may be reviewed by ethics committees or regulatory authorities

Results may be published or presented at scientific meetings, but you will not be identified.

Who is organising and funding the study?

This study is organised by the University Hospital Virgen de las Nieves, Granada.

Who has reviewed the study?

This study has been reviewed and approved by the appropriate Research Ethics Committee.

CONSENT DECLARATION

I, (Participant Name): _____

Confirm that:

- I have discussed the study with the research team
- I have received and understood the written information provided
- I have had the opportunity to ask questions and received satisfactory answers

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- I understand that participation is voluntary
- I understand that I may withdraw at any time without affecting my care

I freely agree to participate in this study.

Participant Signature: _____

Name: _____

Date: _____

Investigator Signature: _____

Name: _____

Date: _____