hm hospitales

NIP:
SURNAME:
NAME:
BED NUMBER:
DATE OF ADMISSION:

Consent for High-Intensity Focused Ultrasound treatment (HIFU) por Parkinson´s disease

PHYSICIAN WHO INFORMS:

SURNAME: …… NAME: ……..

You suffer from a Parkinson's disease whose symptoms may cause inability in performing several daily life activities. Despite having tried different medication therapies, treatment has managed to significantly improve your situation. Your neurologist considers that you may benefit from the treatment with **High-Intensity Focused Ultrasound (HIFU)**. This procedure consists of causing a milimetric lesion by ultrasound in a nucleus of the brain called **subthalamic nucleus** (this injury is called "subthalamotomy"). **The purpose** of this treatment is to reduce the abnormal activity of certain brain areas, which is causing some of the motor symptoms in your disease. The final aim is to improve your symptoms and allow you to enjoy a better quality of life. The lesion in this nucleus to treat Parkinson's disease have been caused for years, however, the ultrasound allows us to cause the lesion without surgery, therefore doing so without any cranial incision significantly reduces the risk of complications.

Regarding this treatment offered, there have been promising results in short and mid-term so far. It is important to know that the improvement will be reflected almost exclusively in the opposite side of the brain where the injury is made.

The type of procedure performed will have an estimated duration of 4-6 hours and you will be conscious during most part of the intervention. First, you should shave all the hair in your head and we will put a stereotaxia frame (a helmet to attach your head to the MRI scan and avoid any movement). You will be wearing compression stockings to avoid the risk of thrombosis due to immobility. Afterwards, you will be placed in the MRI scan where the procedure will take place. You will be ensured comfort and well-being at all times and you will have the possibility of communicating with the medical team directly or by pressing an alarm button with a device you will have in your hand. It is very important that you stay as still as possible when requested. During the procedure, we will evaluate the improvement of your symptoms in different periods or the appearance of any undesired effect of the treatment.

What are the potential risks?

Despite the correct performance of the technique, there could be complications or undesired effects:

- Associated with the MRI: you may feel anxiety or claustrophobia, do not hesitate to let us know if that is the case.
- Associated with the ultrasounds: you may feel a flushing sensation in your head, headache, disorientation, feeling of dizziness or lightheadedness, tingling sensation in your head, nausea or even vomit. You must inform us immediately if you are nauseous.
- Associated with the procedure of subthalamotomy: alteration of speech, paralysis of the limbs in the treated side, imbalance or pain in the opposite side of the lesion.

- There is a possibility that the tremor, rigidity or slowness may reappear a few weeks after the treatment although this possibility is low, around 10% to 20% according to studies. In these cases, a new intervention to improve the symptoms may be considered.

Although these effects are generally considered temporary or well tolerated, there could appear **serious** events such as intracranial bleeding or cerebral infarction in the treated area. These complications could leave sequelae or even cause death. The most common side-effects are of **small importance** or temporary, such as small hematomas or transitory disorientation.

Before signing this document, if you would like to have more information or have any questions, do not hesitate to ask us.

The patient Mr. /Mrs. /Ms. ……, or his/her legal representative ……, declares that:

1. **I HAVE BEEN PROVIDED WITH INFORMATION** about the proposed procedure and its possible alternatives.
2. **I HAVE BEEN DULY INFORMED** and I have had the opportunity to sort out all my doubts about the procedure.
3. **I FREELY PROVIDE MY CONSENT** to perform the proposed procedure and I am aware of my right to remove my authorization at any moment prior to the procedure without providing explanations.

In _____, on (day) _____ (month) _____(year)_____

SIGNATURE OF THE PATIENT OR LEGAL REPRESENTATIVE

ID nº _____

THE INFORMANT PHYSICIAN

Registration number: ……

REJECTION / REVOCATION OF CONSENT

The patient Mr. / Mrs. / Ms. ……, or his / her representative Mr. / Mrs. / Ms. …… expressly manifest my rejection / revocation to perform the proposed procedure.

In _____, on (day) _____ (month) _____(year)_____

SIGNATURE OF THE PATIENT OR LEGAL REPRESENTATIVE

ID nº _____

THE INFORMANT PHYSICIAN

Registration number: ……