TREMOR for patients

Safety and effectiveness of frameless linac-based stereotactic radiosurgery on tremor in patients with essential tremor or Parkinson's disease

Background

In this study, we are exploring the use of stereotactic radiosurgery to treat tremor in patients who have tremor dominant Parkinson's disease or essential tremor.

There are some patients who do not respond to, tolerate or are unsuitable for conventional medical drug therapy. For these patients, a surgical procedure (deep brain stimulation) where electrodes or needles are placed into the central part of the brain and connected to a stimulator (a device which is inserted into the chest wall) can be considered. However, some patients are not able to have this procedure because of advancing age and/or poor health, and there are also some patients who decline surgery.

Stereotactic radiosurgery is a non-invasive alternative to deep brain stimulation for the treatment of tremor in these patients. It is a highly focused form of radiation therapy that delivers high doses to a specified target whilst sparing surrounding tissue and organs. This technique has been used for many decades to treat both benign (non-cancerous) and malignant (cancerous) brain conditions. The advantages of stereotactic radiosurgery over deep brain stimulation are that it is non-surgical, there is no risk of bleeding or infection, it does not require placement of a device into the body, it is cost-effective and it can be used in patients with advanced age or those who are on anticoagulation.

Stereotactic radiosurgery has been utilised internationally for the treatment of tremor. However, this has mostly been delivered using a system called Gamma Knife. Our study is exploring the use of a different delivery system called a linear accelerator or 'linac'. A linac, unlike the Gamma Knife, generates x-rays from electricity and is very similar to the radiation delivery systems used widely in conventional radiation therapy for cancer treatment.

As with any treatment, there are possible risks and disadvantages associated with this study treatment which should be considered before agreeing to participate in this research. A complete overview of the risks involved is included in the Participant Information Sheet and Consent Form which will be provided by the study team if the study is suitable for you.

Treatment

The treatment in this study is frameless linac-based stereotactic radiosurgical thalamotomy that is delivered in a single treatment session at Icon Cancer Centre Richmond.

Participation

Participation in this study is voluntary, meaning you do not need to take part if you do not wish to. This study may be suitable for you if you:

- Are 18 years of age or older
- Have received a clinical diagnosis of essential tremor or tremor dominant Parkinson's
- Have tremor of at least one upper limb resulting in significant disability despite optimal medical treatment
- Have a medication refractory tremor or are intolerant to the medications
- Are unable or choose not to have surgery
- Are able to have and tolerate an MRI scan

All participants will have their case discussed prior to treatment in a multidisciplinary group, which includes a radiation oncologist, neurologist, neurosurgeon, neuropsychiatrist, and neuropsychologist, to ensure suitability for the treatment.

Costs

Participants will not be paid to take part in this study, but all treatment and study-related tests will be provided with no out of pocket costs including:

- Planning scans and delivery of treatment
- MRI scans
- All follow-up study visits

You do not need private health insurance to be considered for participation in this trial.

For more information

For more information about this study, please contact a member of the TREMOR study team at Icon Cancer Centre Richmond on 0417 657 828 or via email at vic.research@icon.team.

ICC111627 TREMOR Research Flyer – Information for Patients, V3, 19 July 2022
This study has been approved by the Monash Health Human Research Ethics Committee.

iconcancercentre.com.au

Funding for TREMOR clinical research trial was provided by the Epworth Medical Foundation, Icon Cancer Foundation and supported in kind by Icon Cancer Centre. TREMOR Summary Information for patients

ICC AUS V3.0 111627 19072022