Doctor's Note — Clinical Trial Summary

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TRIAL

Melphalan Chemoreduction for Ocular Melanoma

NCT ID: NCT05893654 Phase: PHASE1 / PHASE2 Sponsor: Hospital das Clínicas de Ribeirão Preto Status: Enrolling By Invitation

SUMMARY

The goal of this clinical trial is to investigate a new approach for treating large uveal melanomas, a type of eye cancer. The study aims to determine the effectiveness of using intra-arterial melphalan, a chemotherapy drug, to reduce tumor thickness, allowing for subsequent radiation therapy using a Ru-106 plaque.

The main questions this trial seeks to answer are:

* Can intra-arterial melphalan effectively reduce the thickness of large uveal melanomas?
* Is the combination of intra-arterial melphalan and brachytherapy a safe and effective treatment option for these tumors?

Participants enrolled in the trial have clinically diagnosed choroidal melanoma with tumor thickness equal to or greater than 8.00 mm. They will undergo a procedure where the chemotherapy drug is injected directly into the blood vessels that supply the tumor. After a few weeks, they will receive the radiation treatment using a small device placed on the eye. Throughout the trial, participants will have different tests to monitor the tumor and their vision, such as ultrasound scans, pictures of the inside of the eye, and a test called electroretinography (ERG) to check the function of the retina. These tests will be done at the start of the trial and at 1, 3, and 6 months later to track the progress of the treatment.

KEY ELIGIBILITY CRITERIA

- * Age equal to or higher than 18 years
- * Diagnosis of choroidal melanoma with a thickness equal to or higher than 8 mm on ultrasound evaluation
- * Comprehension and signature of the informed consent
- * Adequate pupil dilation and sufficient cooperation to carry out the complementary exams
- * Choroidal melanomas with a greatest basal diameter higher than 18mm
- * Any clinical condition that impairs fundus documentation or patient follow-up
- * Medical or psychological conditions that prevent comprehension and signature of the informed consent
- * Pregnancy, breastfeeding, or plans of getting pregnant in the next year
- * Past medical history of allergic reactions or hypersensitivity to melphalan

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