Doctor's Note — Clinical Trial Summary

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TRIAL

PHP and Immunotherapy in Metastasized UM

NCT ID: NCT04283890 Phase: PHASE1 / PHASE2 Sponsor: Leiden University Medical Center Status: Active Not Recruiting

SUMMARY

Melanoma of the eye (ocular/uveal melanoma) is an uncommon type of cancer that is associated with a high mortality. It usually disseminates rapidly throughout the body, most commonly to the liver and lungs. In this study a combination therapy with immunotherapy (ipilimumab with nivolumab) and chemotherapy (melphalan) will be assessed for the treatment of disseminated uveal melanoma. Melphalan will be administered selectively to the liver via percutaneous hepatic perfusion, limiting the systemic effect of chemotherapy. With this treatment combination we aim to find a treatment for disseminated uveal melanoma, both in the liver as in the other organs.

KEY ELIGIBILITY CRITERIA

- 1. Age between 18-75 yrs
- 2. World Health Organization (WHO) Performance Status 0 or I
- 3. 50% or less histologically or cytologically confirmed unresectable metastatic uveal melanoma in the parenchyma of the liver
- 4. Hepatic metastases, confined to or predominantly in the liver
- 5. No prior systemic treatment (including chemotherapy, vaccine therapy, monoclonal Ab treatment, IL-2)
- 6. Local pre-treatment of uveal melanoma metastases is allowed (resection and/or thermal ablation), except for chemotherapy containing procedures (e.g. chemoembolization) and radio-embolization, and as long as patients have progressed with measurable disease according to RECIST 1.1
- 7. No concurrent systemic immunosuppressive medications e 10mg/day prednisone or equivalent. Topical, inhaled, nasal and ophthalmic steroids, and adrenal replacement therapy are allowed.
- 8. Screening laboratory values must meet the following criteria: WBC e 2.0x109/L, Neutrophils e 1.0x109/L, Platelets e 100 x109/L, Hemoglobin e 6.5 mmol/L, Creatinine d 2x ULN, AST d 2.5 x ULN, ALT d 2.5 x ULN, Total bilirubin d 1.5 X ULN, INR and PTT in normal range, LDH \< 2xULN
- 9. Women of child bearing potential (WOCBP) must agree to use a reliable form of contraceptive as described in paragraph 5.4.
- 10. Men must agree to the use of male contraception as described in paragraph 5.4.

Total sites: 1 | 0 currently recruiting

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