Doctor's Note — Clinical Trial Summary

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TRIAL

Adjuvant Melatonin for Uveal Melanoma

NCT ID: NCT05502900 Phase: PHASE3 Sponsor: Gustav Stalhammar Status: Recruiting

SUMMARY

Uveal melanoma (UM) is the most common type of cancer inside the eyes of adults. Almost half of all patients diagnosed with UM will eventually develop metastases. Once metastases occur, the median patient survival is short.

In this trial, we will test if treatment with Melatonin after primary tumor diagnosis can prevent or delay the development of metastases. 100 patients diagnosed with primary UM will be randomized to either treatment with Melatonin tablets (20 mg at night), or to a control group. Both groups will be followed for 5 years. At 5 years, the number of patients that have developed metastases in the Melatonin and control groups will be compared (primary outcome measure).

KEY ELIGIBILITY CRITERIA

- 1. The patient is e18 years
- 2. The patient has given his/her written informed consent to participate in the trial.
- 3. The patient has a melanoma originating in the choroid or in the ciliary body, as diagnosed by clinical methods and/or histological examination.
- AND at least one of the following 7 items:
- 4. The patient's tumor is of size category T3d or higher, or stage IIIB or IIIC according to the American Joint Committee on Cancer (AJCC, version 8) criteria.
- 5. The patient's tumor is large according to modified criteria from the Collaborative Ocular Melanoma Study (COMS), i.e. largest basal diameter \>16 mm or apical thickness \>8 mm.
- 6. The patient's tumor was of size category T2a before plaque brachytherapy and has then recurred.
- 7. The patient's tumor has an epithelioid cell type (\>5 epithelioid cells per high power field and \>90 % of tumor cells epithelioid).
- 8. The patient's tumor has a low immunohistochemical expression of BAP1.
- 9. The patient's tumor has more than 9 mitoses per high power field.

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting