A Randomised Trial of Post-Operative Radiation Therapy Following Wide Excision of Neurotropic Melanoma of the Head and Neck (RTN2)

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Background and rationale
The management of stage I neurotropic melanoma has traditionally been with surgery. Recommendations are that surgical margins should be at least 1-2 cm. There are, however some patients where this margin is not achievable due to the location of the tumour close to important anatomical structures. Uncontrolled studies suggest that radiation therapy may reduce the risk of local relapse in those patients although there are no randomised trials to confirm this hypothesis. The purpose of this trial is to verify that radiation therapy has a role in the local management of neurotropic melanoma in the postoperative setting.

Study Objectives
To determine the effect of having post-operative radiation therapy following surgery on time to local relapse, relapse free survival, overall survival, cancer specific survival, patterns of relapse, late toxicity, quality of life.

Study Hypothesis
Radiation therapy following surgery improves local control.

Study design
Two-arm, multicentre, open label randomised trial.

Schema

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* Resection of all palpable and visible disease without microscopic residual disease
Patient Accrual

The total patient accrual for this trial will be 100 patients accrued over five years.

Inclusion Criteria

Patients may be included in the trial only if they meet all of the following criteria:

- Aged 18 years or older
- Has provided written informed consent for participation in this trial
- Histologically confirmed neurotropic primary melanoma
- Tumour located above the clavicle and below the jaw or occiput (neck primary) or above the jaw/occiput (head primary)
- Complete macroscopic resection of all known disease with negative microscopic margins
- No previous surgery for melanoma (other than complete macroscopic resection as stated above) (i.e. Not recurrent disease)
- No evidence of in-transit, nodal or distant metastases as determined by clinical examination, and any form of imaging.
- ECOG performance status score of 2 or less
- Life expectancy greater than 6 months
- Patients capable of childbearing are using adequate contraception
- Available for follow up

Exclusion Criteria

Patients who fulfil any of the following criteria are not eligible for admission to trial:

- Women who are pregnant or lactating.
- Intercurrent illness that will interfere with the radiation therapy such as immunosuppression due to medication or medical condition.
- Clinical and/or MRI evidence of a named cranial or cervical nerve involvement by tumour
- Inability to localise surgical bed on any form of imaging and/or surgical margins (cm) not known
- Previous radical radiation therapy to the head and neck, excluding superficial radiation therapy to cutaneous SCC or basal cell carcinoma, which is not within or overlapping the tumour bed.
- High risk for poor compliance with therapy or follow-up as assessed by investigator
- Patients with prior cancers, except: those diagnosed ≥ 5 years ago with no evidence of disease relapse and clinical expectation of relapse of less than 5%; prior successfully treated Level 1 cutaneous melanomas ≥ 2 years ago; or non-melanoma skin cancer; or carcinoma in situ of the cervix.
- Albinism.
- Participation in other clinical trials with the same primary endpoint.
Study Contacts

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