ANZMTG Australia and New Zealand Melanoma Trials Group

The HAIR SPARE Study

A feasibility study of hair sparing whole brain radiotherapy for brain metastases with volumetric modulated arc therapy (VMAT).

ANZMTG 01.07 SS 01.13

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Background

Whole Brain Radiotherapy (WBRT) is a common palliative treatment for brain metastases (BMs). Traditional WBRT leads to acute epilation and complete alopecia, affecting patient quality of life (QoL).

Volumetric modulated arc therapy hair sparing whole brain radiotherapy (VMAT HSWBRT) may allow hair sparing (HS) by reducing the dose to hair follicles as compared with traditional WBRT using open lateral fields. This technique also allows for simultaneous integrated boost to macroscopic BMs on MRI, negating the need for stereotactic radiosurgery on another machine.

This feasibility study is a sub-study of the ANZMTG 01.07 Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma (WBRTMel), a randomised phase III trial. The Hair Spare study has **ANZCTR Trial Registration (ACTRN12617000507381).**

Hypothesis

The primary hypothesis is that VMAT HSWBRT will spare scalp hair, assessed by cross-section trichometry measurement (CTM) and a dermatologist at 4 weeks post treatment, without compromising brain control at 3 months post treatment.

Methods

Any patients with BMs from any solid tumour who require WBRT are eligible. The total patient accrual required for this trial is 15 patients, 13 patients with hair worth conserving and 2 bald control patients to assess the skin dose delivered. Patients are treated with VMAT WBRT 30Gy in 15 fractions using arcs, with Simultaneous Integrated Boost (SIB) 45 Gy in 15 fractions simultaneously to mets. Patients are assessed by a dermatologist and hair density measurements are conducted by CTM. Brain control is assessed at baseline and 3 months post treatment using MRI. QoL is assessed at baseline, 1 month and 3 months post treatment using the Chemotherapy-Induced Alopecia Distress Scale, the EORTC QLQ-C15-PAL+4 and a Visual Analogue Scale.

VOLUMETRIC MODULATED ARC THERAPY HAIR SPARING WHOLE BRAIN RADIOTHERAPY (VMAT HSWBRT) WITH HIPPOCAMPAL SPARING AND SIMULTANEOUS INTEGRATED BOOST for 3 brain metastases ISODOSE DISTRIBUTION

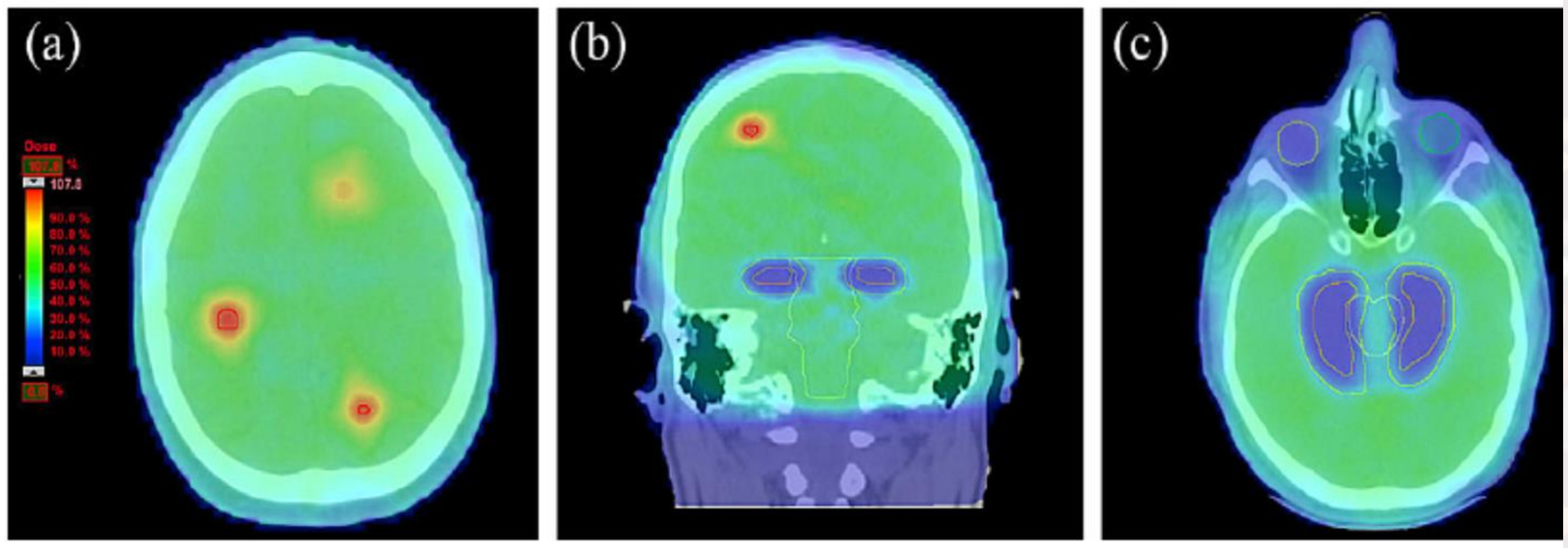


Fig. 1. Examples of isodose distributions for whole brain radiotherapy with hippocampal avoidance and simultaneous integrated boost for three brain metastases using volumetric modulated arc therapy. (a) Axial image with three metastases. (b) Coronal image with one metastasis and the hippocampi. (c) Axial image with the hippocampi and eyes.

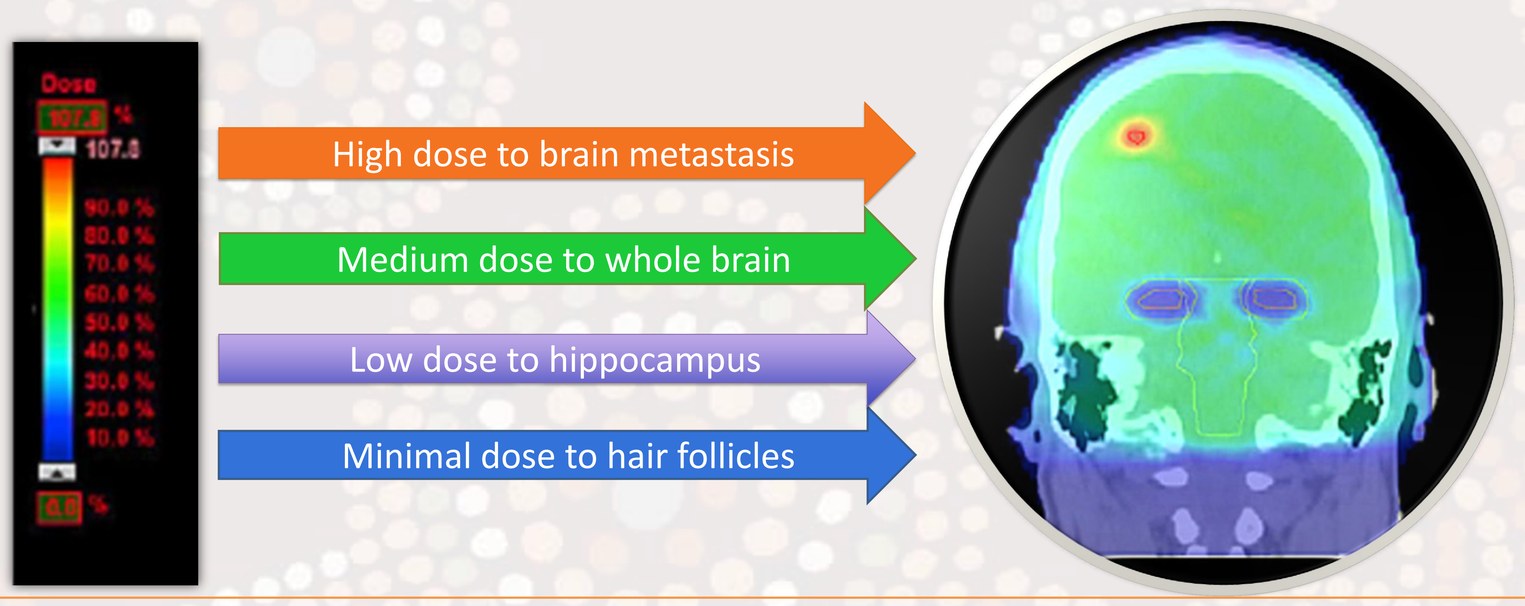


Fig. 2. Isodose distribution highlighted for each structure on a coronal image.

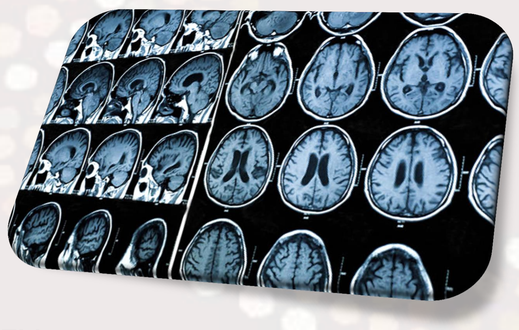
The Hair Spare Study Endpoints

- **Primary Endpoint**

VMAT HSWBRT sparing of scalp hair at 4 weeks post treatment as determined by CTM compared with baseline.

- **Secondary Endpoints**

1. **Oncological** - assessed by routine MRI at 3 months
   - In-brain local/distant progression free survival
   - In-brain overall progression free survival
   - Efficacy in preventing distant in-brain recurrence
   - Overall survival
2. **Hair Sparing**
   - Sparing of scalp hair at 4 weeks post VMAT WBRT by CTM
   - Patient perception of hair shedding eg. the use of head coverings, wigs, etc
   - Impact on QoL
   - Independent assessment of cosmesis (using photography)
   - Presence of follicular ostia as assessed by dermatologist



HAIR SPARE STUDY PATIENT VISITS

ASSESSMENTS:

- Dermatologist Assessment of skin/hair/scalp
- Photography of scalp to assess hair loss
- Hair measurement with CTM
- Brain MRI scans
- Quality of life questionnaires

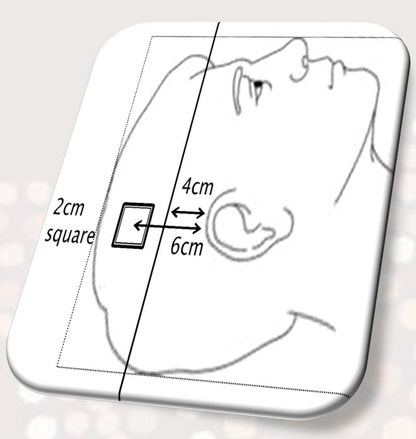
BASELINE

1 MONTH POST VMAT HSWBRT

3 MONTHS POST VMAT HSWBRT

Cross Section Trichometry

The HairCheck© device will be used to measure the density of sup-scalp hair within a 2cm square to determine the cross section trichometry at baseline, then 4 weeks and 3 months post treatment. Hair loss will be assessed.



THE HAIR SPARE STUDY IS CURRENTLY OPEN AND RECRUITING!

Patients may be eligible if they:

- **Require whole brain radiotherapy for brain metastases from any solid organ cancer**
- **Have scalp hair (of at least 2.5cm length) worth saving**
- **Have not received chemotherapy in the past 4 weeks**

The Hair Spare trial is open at the Mater Sydney Hospital in North Sydney. Four (4) patients have been recruited since the study opened in February 2017. The Australian and New Zealand Melanoma Trials Group (ANZMTG) of the University of Sydney is sponsor and trial coordinating centre.

ONLY 15 PATIENTS ARE REQUIRED TO BE TREATED
At The Mater Sydney Hospital, North Sydney

THE UNIVERSITY OF SYDNEY

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Australian Government Cancer Australia

For further interest

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