

Stereotactic Ablative Radiotherapy (XRT) and Immunotherapy for Oligometastatic Extracranial Melanoma

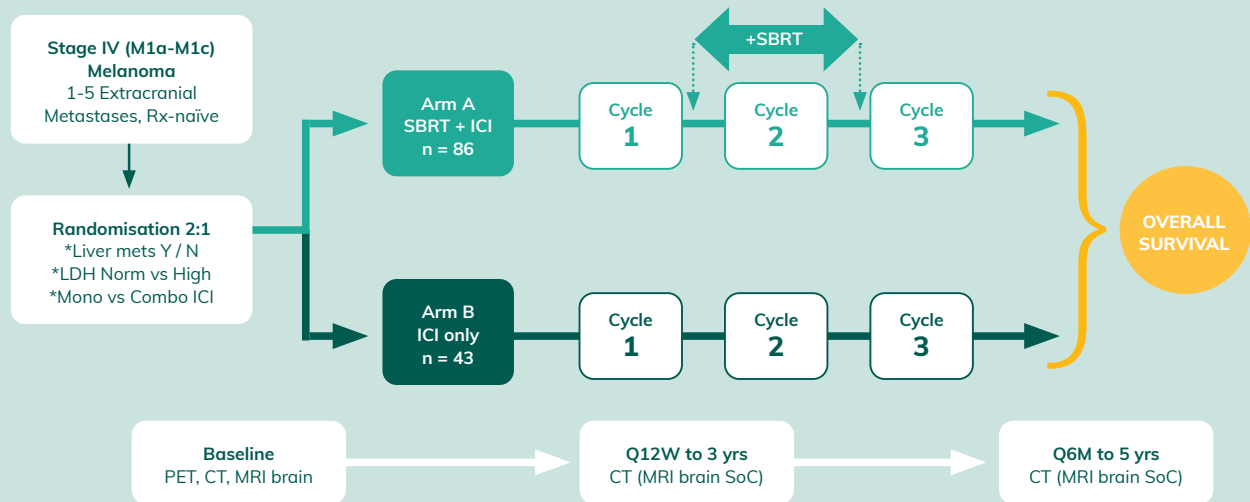
AXIOM is a phase II, multicentre, randomised trial designed to evaluate the effectiveness and safety of upfront SBRT to all radiologically identified metastasis with immunotherapy over immunotherapy alone in patients with 1–5 extracranial melanoma oligometastases.

Eligible participants will be randomly assigned in a 2:1 ratio (Arm A : Arm B) to one of two treatment arms:

Arm A Immunotherapy* + SBRT
(between Immunotherapy Cycle 1 and 3)

Arm B Immunotherapy* alone

*Standard of Care Immunotherapy



PRIMARY OBJECTIVE

To assess the overall survival (OS) of concurrent SBRT and immunotherapy compared to immunotherapy alone

KEY ELIGIBILITY

- First presentation of AJCC Stage IV (any N, M1a-M1c), histologically confirmed (cutaneous, acral or unknown primary melanoma) with 1-5 extracranial oligometastases and considered unresectable. Prior surgery for single resectable metastases is permitted.
- No evidence of brain metastases
- Primary lesion and/or up to 4 in-transit metastases permitted in addition to distant metastases
- Prior systemic therapy and/or radiotherapy for Stage I–III permitted (previously irradiated sites must not be current baseline lesions)
- At least 1 measurable target lesion per RECIST version 1.1
- All metastases must be treatable with a minimum SBRT biologically effective dose (BED) 48Gy10

RECRUITING SITES	STATE / COUNTRY	REFER TO	ROLE
Melanoma Institute Australia	NSW Australia	Angela Hong → Georgina Long → Alex Menzies →	Radiation Oncologist Medical Oncologist Medical Oncologist
Westmead Hospital	NSW Australia	Tim (Wei) Wang → Matteo Carlino →	Radiation Oncologist Medical Oncologist
Princess Alexandra Hospital	QLD Australia	Mark Pinkham → Wen Xu →	Radiation Oncologist Medical Oncologist
The Alfred Hospital	VIC Australia	Jeremy Ruben → Andrew Haydon →	Radiation Oncologist Medical Oncologist
Princess Margaret Cancer Centre	ON Canada	Philip Wong → Marcus Butler →	Radiation Oncologist Medical Oncologist

TRIAL INFORMATION

ClinicalTrials.gov ID [NCT06767306](https://clinicaltrials.gov/ct2/show/study/NCT06767306)

Trial Sponsor Melanoma Institute Australia

Lead Investigator Angela Hong

Scientific Title A Phase II, Multicentre, Non-Comparative, Randomised Controlled Trial of Stereotactic Ablative Body Radiotherapy and Immunotherapy versus Immunotherapy Alone in Patients with Treatment Naïve Oligometastatic Extracranial Melanoma

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