SMART (TROG 23.02): A MULTI-CENTRE PROSPECTIVE TRIAL OF SINGLE AND MULTI-FRACTION PREOPERATIVE RADIOSURGERY FOR BRAIN METASTASES

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Background: Preoperative radiosurgery (PreOp-SRS) for brain metastases (BM) is increasingly utilised supported by large multi-institution retrospective and prospective non-randomised reports with results from phase III trials awaited. Most of the prospective protocols and reported data involves single fraction PreOp-SRS. Retrospective results suggest that multi fraction PreOp-SRS may have some benefits compared with single fraction PreOp-SRS

Objective: The study will prospectively analyse outcomes from single and multi fraction PreOp-SRS for BM in a randomised fashion evaluating if multi fraction PreOp-SRS results in higher cavity local control (LC) rates than single fraction PreOp-SRS

Patients & Methods : SMART is a multi-centre randomised phase II prospective clinical trial (HREC/120590/PMCC). Patients with primary solid cancer diagnosis and radiologically confirmed BM who have been recommended surgery for up to two BM will be eligible. Exclusion criteria include lesion > 4cm, symptoms mandating emergency surgery, prior whole brain radiotherapy, SRS to the index BM(s) or presence of leptomeningeal disease (LMD). 73 eligible patients will be randomised to single fraction (15-20 Gy) or 3 fraction (24 or 27 Gy) PreOp-SRS followed by resection of the BM ideally within 7 days up to maximum of 14 days after SRS. All patients will undergo Magnetic Resonance Imaging (MRI) of the brain within 1-3 days after surgery then reviewed clinically and with MRI 3 monthly for 12 months. A 2:1 randomisation will be performed using the method of minimisation to optimise balance between the stratification factors and desired allocation ratio. Primary endpoint will be measured as cavity LC at 12 months after surgery. Secondary endpoints include overall survival, neurological death, LMD, adverse events and QOL.

Conclusion: PreOp-SRS is increasingly utilised however evidence for the most optimal fractionation schedule from prospective randomised trials is lacking. Funding has been secured allowing the opening of the study at three Australian centres in 2026.

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