

CORE: A randomised trial of COventional care versus

Radioablation (stereotactic body radiotherapy) for

Extracranial oligometastases

Introduction: Stereotactic body radiotherapy (SBRT) is increasingly becoming a key treatment option for patients with oligometastatic disease. However, a lack of randomised data limits interpretation of results from retrospective and prospective cohort studies. Whilst these studies indicate higher rates of local control with acceptable toxicity the true benefit of adding SBRT to standard therapy remains unclear. Potential therapeutic benefit may also vary between tumour sites (underlying tumour biology, natural disease course).

CORE investigates whether the addition of SBRT to standard therapy improves patient outcomes in common primary tumour sites where oligometastatic disease is encountered (prostate, breast, NSCLC).

Methods: CORE is a phase II/III multi-centre, randomised controlled trial comparing standard of care (SOC) with or without

SBRT for extra-cranial metastases. Patients with primary breast, prostate or NSCLC presenting with ≤ 3 extracranial, metachronous, oligometastases, all suitable for SBRT, are eligible. Patients are randomised 1:1 to either SOC + SBRT or SOC alone, choice of SOC is at local clinician's discretion, defined prior to randomisation. All patients are reviewed every 3 months with clinical examination and tumour markers during years 1 and 2 and 6 monthly thereafter to 5 years. The primary endpoint of the trial is progression free survival.

Results: CORE opened for recruitment in the UK in October 2016 and August 2017 in Australia. To date 22 centres are open (18 UK, 4 Australia). Recruitment is on target (206) with a total of 95 patients

randomised; 72 prostate, 14 breast and 9 lung.

Conclusion: The CORE Trial Management Group aim to build on the success of prostate recruitment to enhance and improve accrual for the breast and lung cohorts. If the CORE phase II aims are achieved additional funding will be sought to roll the study into parallel tumour-site specific phase III trials.