

CORE - Randomised trial of Conventional care versus Radioablation (stereotactic body radiotherapy (SBRT)) for Extracranial metastases

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Abstract

Objectives: Phase 2 SBRT studies have shown that patients with =3 metastases have better PFS and overall survival (OS) than patients with more widespread disease, and that breast cancer patients may fare best. High rates of local control are seen, together with acceptable rates of toxicity for oligometastases. Progression-free survival (PFS) rates in these studies are better than would usually be expected in stage 4 disease; however, a lack of randomized data limits interpretation. A control group is required to evaluate the true benefit of adding SBRT to systemic treatment and which patient groups are most likely to benefit. The potential therapeutic benefit of adding SBRT to standard therapy may thus vary between tumour sites, reflecting the different underlying tumour biologies, immunology and natural disease course.

Methods: CORE (CRUK/14/038) is a phase II/III, multi-centre, non-blinded, parallel group randomised controlled trial in patients with breast, prostate or non-small cell lung (NSCLC) cancer comparing standard of care therapy (SOC) with or without SBRT for extra-cranial metastases. A total of 206 patients will be recruited in the phase II trial; Eligible patients are those with either primary breast, prostate or NSCLC who have presented with =3 extra-cranial metachronous oligometastases, all suitable for SBRT. A maximum of 2 different organ systems (e.g liver, lung, bone, nodal) may contain metastases but the total number of lesions must not exceed 3. There must be no previous treatment for metastatic disease, and a =6 months disease free interval (DFI) for breast and prostate patients; =4 months for NSCLC from completion of primary radical treatment. Main exclusion criteria include intra-cranial metastases, malignant pleural effusion or peritoneal disease, a metastasis >6cm (>5cm for lung), and prior radiotherapy to a site that precludes safe delivery of SBRT. Patients will be randomised (1:1 ratio) to either SOC alone or SOC and SBRT. Choice of SOC is at the discretion of the treating oncologist and defined per patient prior to randomisation. It may include any standard therapy that is clinically appropriate e.g. chemotherapy, biological therapy, endocrine therapy, palliative radiotherapy or observation. Patients randomised to SBRT will receive a dose and fractionation regimen dependent on the metastatic site and proximity to dose limiting organs

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and normal tissues. Staging and follow up imaging protocols will be tumour type dependent.

Results: Primary endpoint is to evaluate if the addition of SBRT to SOC improves PFS in patients with a limited burden of oligometastatic disease. Secondary endpoints include the dose level achievable within the dosimetric constraints, evaluation whether the addition of SBRT to SOC improves OS, lesion local control rates in those receiving SBRT, acute and late toxicity associated with the addition of SBRT to SOC, and quality of life in patients receiving SBRT compared to those receiving SOC alone. The study will also evaluate if the addition of SBRT to SOC improves freedom from widespread metastatic disease (FFWMD).

Conclusions: The aim of the CORE phase II is to demonstrate (1) feasibility of randomised recruitment, (2) deliverability of the study in an international multi-centre setting and (3) the activity of SBRT based on PFS and OS across the three tumour types. If all three aims are achieved the trial will be amended to roll into parallel tumour-site specific phase III trials.