CORE: A randomised trial of COnventional care versus Radioablation(stereotactic body radiotherapy (SBRT)) in Extracranial oligometastases (CRUK/14/038)

Chief Investigator: Dr Vincent Khoo **Sponsor**: The Royal Marsden NHS Foundation Trust **Funder**: Cancer Research UK

The CORE trial is currently recruiting patients with **breast cancer**.

Please see below for further details, patient eligibility and trial team contact information.

Background

- 'Oligometastases' describes the concept of an intermediary state where cancer exists as a limited number of metastases before cells acquire the ability to metastasise more widely.
- Successful eradication of disease at oligometastatic stage may improve survival outcomes and even cure for a select few.

Trial Design

- CORE is a phase II/III multi-centre, non-blinded, randomised controlled trial comparing standard of care (SOC) with or without SBRT for extra-cranial metastases.
- Primary endpoint: Progression Free Survival (PFS).
- Target accrual: 206 patients (with breast cancer, prostate cancer or NSCLC).
- The phase II component of CORE aims to demonstrate:
  - Feasibility of randomised recruitment;
  - Deliverability of the study in an international multi-centre setting;
  - SBRT activity based on PFS across the three tumour types.
- If all three aims are achieved additional funding will be sought to roll the study into parallel tumour-site specific phase III trials.

Trial Schema

Patients with breast cancer with ≤ 3 oligometastases

RANDOMISATION
1:1

SOC group
May include chemotherapy, biological therapy, hormone therapy, palliative radiotherapy or observation at investigator's discretion

SBRT + SOC group
- Dose and fractionation dependent on metastatic site
- SBRT to precede SOC

Follow up
- Patients are reviewed every 3 months during years 1 and 2, and 6 monthly thereafter up to 5 years.
- Follow up visits include a clinical exam, tumour imaging scans, and assessment of tumour marker CA 15-3 (where available)

Key Eligibility Criteria

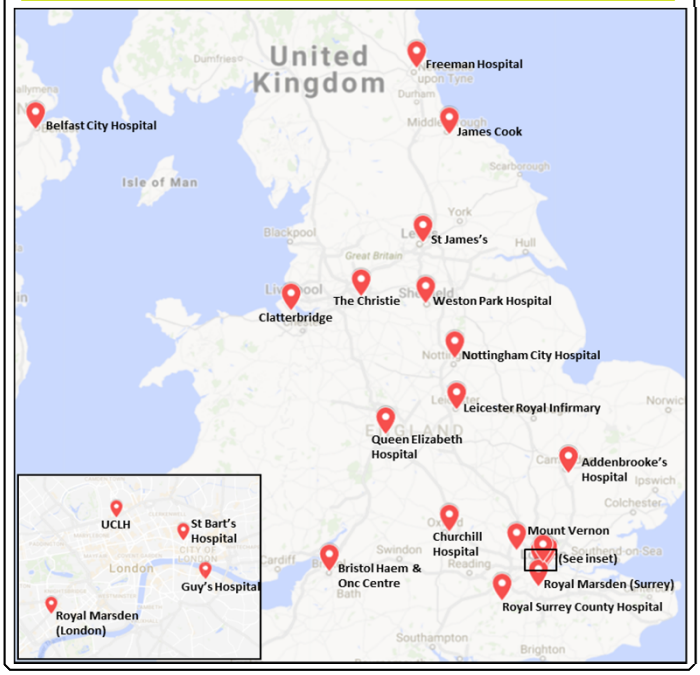
Inclusion Criteria

- Age ≥18 years; WHO performance status 0-2; histological confirmation of primary breast cancer; predicted life expectancy > 6 months.
- ≤ 3 metastatic lesions (total) in ≤ 2 different organ systems; visible, imaging defined metastatic targets suitable for SBRT treatment.
- Prior ablative therapy (e.g. surgery, RFA or SBRT) for metastatic disease is allowed, if this site is controlled on imaging at trial entry.
- Metachronous metastatic disease presentation.
- Disease-free interval from completion of radical treatment to diagnosis of metastases: ≥6 months.
- Systemic therapy naïve in the metastatic setting. Concurrent endocrine therapy with SBRT is allowed. A change in endocrine therapy due to the diagnosis of oligometastatic disease is allowed if trial entry is within 10 weeks of this change.

Exclusion Criteria

- Intra-cranial metastases; Malignant pleural effusion; Malignant peritoneal disease; Any single metastasis >6cm,(>5cm for lung mets).
- Prior radiotherapy to a site that precludes safe delivery of SBRT.
- Loco-regional nodal relapse where surgery is considered the standard of care and is technically feasible. Patients with IMC or SCF lymph node relapses of breast cancer are eligible if SBRT dose constraints can be met. Patients with axillary nodal relapse from breast cancer are excluded.

Current Recruiting UK Centres



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