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 **non-small cell lung 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 NSCLC, breast cancer or prostate cancer).
- 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 NSCLC with ≤ 3 oligometastases

RANDOMISATION 1:1

SOC group
May include chemotherapy, biological 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 with a clinical exam during years 1 and 2, and 6 monthly thereafter up to 5 years.
- Tumour imaging scans are every 3 months in years 1 and 2, every 6 months in year 3, and then annually up to 5 years.

Key Eligibility Criteria

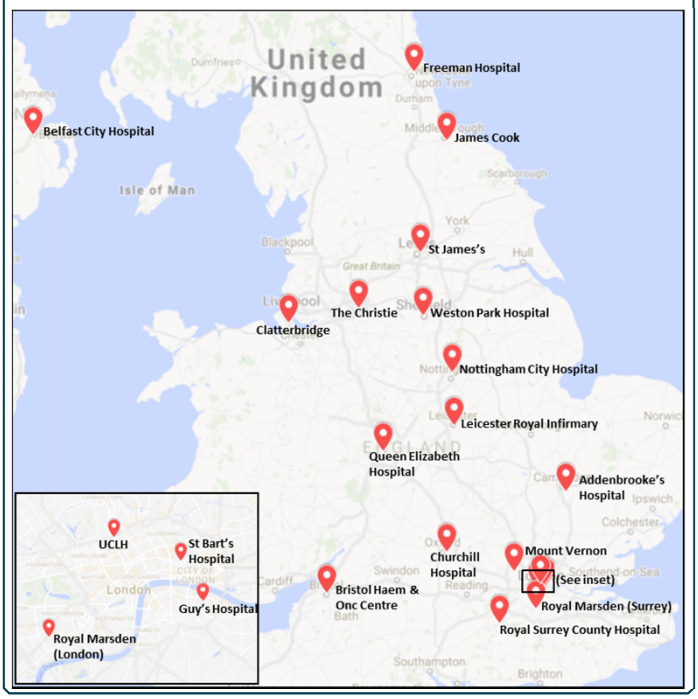
Inclusion Criteria

- Age ≥18 years; WHO performance status 0-2; histological confirmation of primary NSCLC; 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, except synchronous single brain metastasis treated radically along with the primary malignancy.
- Disease-free interval from completion of radical treatment to diagnosis of metastases: ≥4 months.
- Systemic therapy naïve in the metastatic setting.

Exclusion Criteria

- Intra-cranial metastases; Malignant pleural effusion; Malignant peritoneal disease; Any single metastasis >6cm,(>5cm for lung mets).
- Prior radiotherapy precluding safe delivery of SBRT.
- Loco-regional nodal relapse where surgery is considered the standard of care and is technically feasible.

Current Recruiting UK Centres



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