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Single fraction versus multifraction radiotherapy for patients with metastatic spinal cord compression

Submission date 12/05/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/06/2009	**Overall study status** Completed	
Last Edited 07/05/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-single-radiotherapy-treatment-with-course-of-radiotherapy-treatments-cancer-pressing-on-spinal-cord-SCORAD-III

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00727584

Protocol serial number

N/A

Study information

Scientific Title
A randomised phase III trial of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression

Acronym
SCORAD III

Study objectives
This is a non-inferiority trial to show that ambulatory status using 8 Gy in one fraction is no worse than 20 Gy in five fractions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West London REC 1, 03/11/2009, ref: 09/H0722/76

Study design
Multicentre randomized phase III trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic spinal cord compression

Interventions
Patient randomisation is performed using a 24 hour remote internet based randomisation programme.

Arm 1: External beam multi-fraction radiotherapy: 20Gy/5f
Arm 2: External beam single fraction radiotherapy: 8Gy/1f

Total duration of treatment is approximately one week for Arm 1, and one day for Arm 2. Follow up for both treatment arms is at 1, 4, 8 and 12 weeks after day 1 of treatment.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)

Ambulatory status is determined through phone interviews with the patient or where this is not possible, reviewing the patient notes, applying a simple 4 point ambulatory scale at 8 weeks from day 1 of treatment compared to randomisation.

Key secondary outcome(s))
1. Recovery of and time to ambulation is measured through phone interviews with the patient or where this is not possible, reviewing the patient notes, applying a simple 4 point ambulatory scale at weeks 1, 4, 8, and 12 from day 1 of treatment compared to randomisation
2. Ambulatory status is determined using measured through phone interviews with the patient or where this is not possible, reviewing the patient notes, applying a simple 4 point ambulatory scale at 1, 4, and 12 weeks (where available) compared to randomisation
3. Maintenance of ambulatory status is determined through phone interviews with the patient or where this is not possible, reviewing the patient notes, applying a simple 4 point ambulatory scale at weeks 1, 4, 8, and 12 from day 1 of treatment compared to randomisation
4. Bladder and bowel function is measured through phone interviews with the patient or where this is not possible, reviewing the patient notes, at 1, 4, 8 and 12 weeks from day 1 of treatment compared to randomisation
5. Acute side effects are measured using through phone interviews with the patient or where this is not possible, reviewing the patient notes, applying the Common Terminology Criteria for Adverse Events (CTCAE) scales v4.02 or Radiation Treatment and Oncology Groups (RTOG) Scales at 1, 4, 8 and 12 weeks from day 1 of treatment
6. Quality of life is measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-30) questionnaire at 1, 4, 8 and 12 weeks from day 1 of treatment compared to randomisation. This is either posted to the patient from UCT CTC or administered by the hospital trial team if the patient is an inpatient.
7. Further treatment is recorded using through phone interviews with the patient or where this is not possible, reviewing the patient notes, at 1, 4, 8 and 12 weeks and 12 months from day 1 of treatment
8. Duration of care in hospital, hospice, nursing home or home is determined through phone interviews with the patient or where this is not possible, reviewing the patient notes at 1, 4, 8 and 12 weeks
9. Preferred place of care is determined through phone interviews with the patient at 1, 4, 8 and 12 weeks from day 1 of treatment
10. Overall survival is determined at 12 and 52 weeks through review of patient notes. Alternatively the trial is flagged with the UK Health & Social Care Information Centre for survival data

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Inclusion criteria as of 04/02/2016:
1. Decision to treat made no more than 48 hours prior to treatment of spinal cord or cauda equina (C1 to S2) compression, based on a full spinal MRI or CT scan confirming compression carried out no more than one week prior to treatment
2. Single site of compression or multiple sites that can be treated within a single radiation treatment field
3. Histologically or cytologically confirmed malignant disease, or for prostate tumours a serum PSA >100 ng/ml at any point prior to randomisation (if biopsy done or planned but results not

yet available patients may be entered provided all other inclusion and exclusion criteria are met. Biopsy results must be submitted on the relevant CRF page as soon as they are available)
4. Life expectancy greater than 8 weeks
5. Age greater than or equal to 18 years, either sex
6. Able to give informed consent
7. Willing and able to complete assessment forms

Original inclusion criteria:
1. Proven diagnosis of spinal cord compression on magnetic resonance imaging (MRI) or computed tomography (CT) scan
2. Single site of compression or multiple sites that can be treated within a single radiation treatment field
3. Histologically or cytologically confirmed malignant disease, or for prostate tumours serum prostate specific antigen (PSA) at diagnosis of greater than 100 ng/ml
4. Life expectancy greater than 8 weeks
5. Age greater than or equal to 18 years, either sex
6. Able to give informed consent
7. Willing and able to complete assessment forms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
686

Key exclusion criteria
Exclusion criteria as of 04/02/2016:
1. Patients for whom surgery or chemotherapy treatment is more appropriate
2. Patients with multiple myeloma, lymphoma, leukaemia or glioma
3. Patients who are known to be pregnant
4. Patients undergoing purely prophylactic treatment in the absence of radiological spinal cord or cauda equina compression
5. Patients whose spinal compression site has been treated previously with radiotherapy

Original exclusion criteria:
1. Patients for whom surgery or chemotherapy treatment is more appropriate
2. Patients with multiple myeloma or lymphoma

3. Patients who are known to be pregnant
4. Patients undergoing purely prophylactic treatment for early onset spinal cord compression
5. Patients undergoing treatment for compression affecting the spinal canal below L1

Date of first enrolment
01/09/2009

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
United Kingdom

England

Australia

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre
University College London
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ

Study participating centre
Mater Health Services
Raymond Terrace
Brisbane
Australia
QLD 4101

Sponsor information

Organisation
University College London (UCL) (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C2422/A11408)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/12/2019	04/12/2019	Yes	No
Results article	Quality-of-life outcomes	05/05/2024	07/05/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			01/06/2023	No	Yes
Protocol file		03/03/2013		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes