

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

<b>Submission date</b> 12/05/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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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?
<a href="#">Results article</a>	results	03/12/2019	04/12/2019	Yes	No
<a href="#">Results article</a>	Quality-of-life outcomes	05/05/2024	07/05/2024	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			01/06/2023	No	Yes
<a href="#">Protocol file</a>		03/03/2013		No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes