# A randomised feasibility study of single fraction radiotherapy compared to multi-fraction radiotherapy in patients with metastatic spinal cord compression

| <b>Submission date</b> 04/06/2007 | Recruitment status No longer recruiting | [X] Prospectively registered   |  |  |
|-----------------------------------|---|--------------------------------|--|--|
|                                   |   | Protocol                       |  |  |
| Registration date 23/07/2007      | Overall study status Completed          | Statistical analysis plan      |  |  |
|                                   |   | [X] Results                    |  |  |
| Last Edited                       | Condition category                      | [] Individual participant data |  |  |
| 07/05/2024                        | Cancer                                  |                                |  |  |

#### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-a-single-radiotherapy-treatment-with-a-course-of-radiotherapy-treatments-for-cancer-pressing-on-the-spinal-cord

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

#### Protocol serial number

BRD/07/010

# Study information

#### Scientific Title

A randomised feasibility study of single fraction radiotherapy compared to multi-fraction radiotherapy in patients with metastatic spinal cord compression

#### Acronym

SCORAD feasibility study

#### Study objectives

To examine whether a phase III randomised trial comparing a single fraction of radiotherapy with multi-fraction radiotherapy is acceptable to clinicians and patients.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Cornwall and Plymouth Research Ethics Committee approved before patient recruitment began, ref: 07/H0203/167

#### Study design

Randomized controlled feasibility study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Metastatic spinal cord compression

#### **Interventions**

Radiotherapy (single or multiple fractions):

Arm 1: 20 Gy/5 fractions daily for 5 consecutive days

Arm 2: 8 Gy/1 fraction

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Patient accrual per centre over a 12-month period.

#### Key secondary outcome(s))

- 1. Ambulatory status at 1, 4, 8 and 12 weeks from day 1 of treatment compared to baseline
- 2. Bladder and bowel function at baseline compared to week 1, 4, 8 and 12
- 3. Acute side effects at week 1 and 4 assessed using Radiation Therapy Oncology Group (RTOG) scales
- 4. Quality of life at week 1, 4, 8 and 12, measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) questionnaire
- 5. Further treatment
- 6. Overall survival at 3, 6 and 12 months
- 7. Total number of days spent in hospital
- 8. Preferred place of care
- 9. Number of patients who were eligible but not randomised and reasons for non-randomisation

#### Completion date

31/08/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Proven diagnosis of spinal cord compression on magnetic resonance imaging (MRI)
- 2. Histologically or cytologically confirmed malignant disease
- 3. Life expectancy greater than 1 month
- 4. Aged 18 years or older
- 5. Able to give informed consent
- 6. Willing and able to complete assessment forms

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### Total final enrolment

686

#### Key exclusion criteria

- 1. Patients for whom surgery or chemotherapy treatment is more appropriate
- 2. Patient known to be pregnant

#### Date of first enrolment

01/03/2008

# Date of final enrolment 31/08/2009

# Locations

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre Mount Vernon Hospital Northwood United Kingdom HA6 2RN

# 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/A7932)

#### 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

Not provided at time of registration

# IPD sharing plan summary

#### **Study outputs**

| Output type                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article               | results                       | 03/12/2019   | 04/01/2021 | 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         |                               |              | 26/10/2022 | No             | Yes             |