

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

Submission date 04/06/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00727584

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

Primary study design

Interventional

Study design

Randomized controlled feasibility study

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

All

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
Plain English results			26/10/2022	No	Yes