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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
04/06/2007		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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00727584

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Patient accrual per centre over a 12-month period.

Secondary outcome measures

- 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

Overall study start date

01/03/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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

England

United Kingdom

Study participating centre Mount Vernon Hospital

Northwood United Kingdom HA6 2RN

Sponsor information

Organisation

University College London (UCL) (UK)

Sponsor details

Medical School Administration Gower Street London England

United Kingdom WC1E 6BT

Sponsor type

University/education

Website

http://www.ucl.ac.uk/cancertrials/

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/12/2019	04/01/2021	Yes	No
Plain English results			26/10/2022	No	Yes
Results article	Quality-of-life outcomes	05/05/2024	07/05/2024	Yes	No