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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

Registration date
23/07/2007

Overall study status
Completed

Last Edited
07/05/2024

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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