ISRCTN66281665 https://doi.org/10.1186/ISRCTN66281665

A phase II randomised trial to assess external beam radiotherapy and intraluminal bronchial brachytherapy as re-treatment in patients with lung cancer who have received primary palliative external beam therapy

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 31/10/2019	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LUN/INT

Study information

Scientific Title
A phase II randomised trial to assess external beam radiotherapy and intraluminal bronchial brachytherapy as re-treatment in patients with lung cancer who have received primary palliative external beam therapy

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Lung (non-small cell) cancer

Interventions
Patients with respiratory symptoms requiring re-treatment after palliative external beam radiotherapy are randomised to one of two regimens:

1. External Beam Radiotherapy:
Patients will be treated by the radiotherapist using whatever schedule is thought appropriate. There will be no standardisation of treatment although 20 Gy in five fractions over five to seven days, with appropriate attention to shielding of the spinal cord, where indicated, is recommended.

2. Intraluminal Bronchial Brachytherapy:
Intraluminal Bronchial Brachytherapy 10 Gy at 1 cm. To be carried out as a day case procedure at Cookbridge Hospital, Leeds using fibre-optic bronchoscopy and standard published protocol (Goldman et al, 1993).

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1997

Completion date
07/05/1997

Eligibility

Key inclusion criteria
1. Histologically confirmed non-small cell cancer
2. Respiratory symptoms due to lung cancer
3. Previous palliative external beam radiotherapy
4. Expected survival at least two months
5. When patient requires retreatment, radiotherapist considers suitability for further course of external beam radiotherapy or intraluminal bronchial brachytherapy
6. Well enough to tolerate fibre optic bronchoscopy: at bronchoscopy patient has endobronchial disease and it is still considered that the patient could be treated with intraluminal bronchial brachytherapy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment
01/01/1997

Date of final enrolment
07/05/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Northern and Yorkshire Clinical Trials and Research Unit (UK)

Sponsor details
17 Springfield Mount
Leeds
United Kingdom
LS2 9NG

Sponsor type
Research organisation

Website
http://www.leeds.ac.uk/medicine/nyctru/nyctru_page1.htm

Funder(s)

Funder type
Research organisation

Funder Name
Northern & Yorkshire Clinical Trials and Research Unit (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration