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

Plain English summary of protocolNot 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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration