

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Northern and Yorkshire Clinical Trials and Research Unit (UK)

Funder(s)

Funder type

Research organisation

Funder Name

Northern & Yorkshire Clinical Trials and Research Unit (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration