ISRCTN54145633 https://doi.org/10.1186/ISRCTN54145633

Phase II comparison of accelerated twice-daily compared with once-daily thoracic radiotherapy in limited small-cell lung cancer treated concurrently with etoposide and cisplatin

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
04/10/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0063115998

Study information

Scientific Title

Study objectives
This randomised phase II trial is aiming to assess the acute toxicity of twice-daily and once-daily concurrent chemo-radiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Cancer: Limited small-cell lung cancer

Interventions
Arm A: new total dose of 66 Gy given over 45 days once-daily concurrently with chemotherapy
Arm B: total 45 Gy given over 19 days twice-daily concurrently with chemotherapy

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
etoposide and cisplatin

Primary outcome(s)
Acute toxicity (particularly grade III/IV oesophagitis).

Key secondary outcome(s)
1. Overall survival
2. Response rates

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients who are ≤75 years of age with histologically proven small-cell lung cancer and fully meet the criteria will be approached for consent. 81 Patients in total will be recruited for the trial and 27 will be recruited to the standard arm and 54 to the experimental arm. 25 patients per year.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Oncology
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Christie Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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				Yes	No