A trial comparing conventional fractionation with 'CHART' in the radical treatment of nonsmall cell carcinoma of the bronchus

Submission date	Recruitment status	Prospectively registered
28/02/2001	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
28/02/2001	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
29/10/2019	Cancer	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr James Lyddiard

Contact details

MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers CH01

Study information

Scientific Title

A trial comparing conventional fractionation with 'CHART' in the radical treatment of non-small cell carcinoma of the bronchus

Study objectives

To compare the effectiveness of radical fractionated radiotherapy given daily over six weeks with CHART over 12 days, with respect to survival, local tumour control and morbidity

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) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Cancer

Interventions

Conventional radiotherapy arm - 2 Gy, once daily five days a week over six weeks (large volume - 44 Gy in 22 fractions followed by small volume - 16 Gy in eight fractions)
CHART arm - 1.5 Gy, three time daily over 12 treatment days (large volume - 37.5 Gy in 25 fractions followed by small volume - 16.5 Gy in 11 fractions)

Intervention Type Other

Phase Not Specified

Primary outcome measure

Survival, Local tumour control, Morbidity

Secondary outcome measures Not provided at time of registration

Overall study start date 01/02/1990

Completion date 01/03/1995

Eligibility

Key inclusion criteria

Inoperable non-small cell carcinoma of the bronchus confined to the thorax proven by histology or by unequivocal brush cytology

Participant type(s) Patient

Age group Not Specified

Sex Both

Target number of participants 600

Key exclusion criteria

1. There should be no evidence of distant metastases including supraclavicular nodes;

2. The patient must have no evidence of a pleural effusion unless it can be attributed to a recent surgical intervention;

3. The volume of the site of tumour within the thorax should be such that a radical course of radiotherapy could be given without prejudicing vital structures such as the spinal cord or lung

Date of first enrolment 01/02/1990

Date of final enrolment 01/03/1995

Locations

Countries of recruitment England

United Kingdom

Study participating centre MRC Clinical Trials Unit London United Kingdom NW1 2DA

Sponsor information

Organisation Medical Research Council (MRC) (UK)

Sponsor details 20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type Research council

Website http://www.mrc.ac.uk

Funder(s)

Funder type Research council

Funder Name Medical Research Council (MRC) (UK)

Alternative Name(s) Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location

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