

Completion of documentation of late effects of treatment of patients in both arms of the CHART studies (for previous work, refer to MRC Headoffice)

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/11/2022	Condition category Cancer	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9615854/9005262

Study information

Scientific Title

Completion of documentation of late effects of treatment of patients in both arms of the CHART studies (for previous work, refer to MRC Headoffice)

Study objectives

The CHART trials, the largest of their kind in Europe, have shown an improvement in survival of 10% at 2 years in patients with carcinoma of the bronchus treated with CHART, as compared with conventional radiotherapy. In the head and neck trial, the overall benefit in local tumour control does not reach statistical significance but this is reached in important sub-groups. There is however a reduction in morbidity in this trial giving a therapeutic benefit. To determine the true usefulness of a new radiotherapy schedule and to build on the improvements obtained the effect on therapeutic ratio must be defined over time. During the trial full data has now been gathered and analysed concerned with acute reactions and in the follow up late morbidity and from this data we have been able to make important contributions to radiobiological knowledge in humans particularly by a calculation of the repair half-times of normal tissue being about twice as long as previously known. Recent publications include:

1. Bentzen SM, Saunders MI and Dische S. Repair half-times estimated from observations of treatment-related morbidity after CHART or conventional radiotherapy in head and neck cancer. *Radiother Oncol* 1999; 53:219-226
2. Ataman OU, Bentzen SM, Saunders MI and Dische S. Failure specific prognostic factors after Continuous Hyperfractionated Accelerated Radiotherapy (CHART) or conventional radiotherapy in locally advanced non-small cell lung cancer: A competing risk analysis. *Br J Cancer* 2001; 85: 1113-1118.
3. Bentzen SM, Saunders MI, Dische S and Bond S. Radiotherapy early morbidity in head and neck cancer: quantitative clinical radiobiology as deduced from the CHART trial. *Radiother Oncol* 2000; 60: 123-135
4. Wilson GD, Saunders MI, Dische S, Richman PI, Daly FM and Bentzen SM. BCL-2 expression in head and neck cancer: an enigmatic prognostic marker. *Int J Radiation Oncol Biology Phys* 2001; 49: 435-441.
5. Bentzen SM, Saunders MI and Dische S. From CHART to CHARTWELL in non-small cell lung cancer: clinical radiobiological modelling of the expected changes in outcome. *Clin Onc (Royal College of Radiologists)*-in press
6. Khalil AA, bentzen SM, Bernier J, Saunders MI, Horiot J-C, van den Bogaert W, Cummings PG and Dische S. Compliance to prescribed dose and overall treatment time in five randomised clinical trials of altered radiotherapy fractionation in head and neck cancer. *Int J Radiation Oncol Biol Phys* (submitted 2002).

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

CHART/conventional radiotherapy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The documentation of late effects as specified in the original CHART studies

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1998

Completion date

01/07/2000

Eligibility**Key inclusion criteria**

Locally advanced cancer of the bronchus and in the major head and neck sites

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

49 patients (bronchus) + 379 (head & neck)

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/1998

Date of final enrolment

01/07/2000

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Beatson Oncology Centre

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

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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 (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

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/12/1999		Yes	No
Results article		01/08/2001		Yes	No
Results article		19/10/2001		Yes	No