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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 07/11/2022	**Condition category** Cancer	

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
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 as 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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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

Interventions
CHART/conventional radiotherapy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The documentation of late effects as specified in the original CHART studies

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

Scotland

Study participating centre
Beatson Oncology Centre
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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