

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

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

**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 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

## 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?
<a href="#">Results article</a>		01/12/1999		Yes	No
<a href="#">Results article</a>		01/08/2001		Yes	No
<a href="#">Results article</a>		19/10/2001		Yes	No