# CHARTWEL - Continuous Hyperfractionated Accelerated Radiotherapy Week-End Less

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>	
08/11/2000		Protocol	
Registration date	Overall study status Completed  Condition category Cancer	Statistical analysis plan	
08/11/2000		Results	
Last Edited		Individual participant data	
28/01/2019		Record updated in last year	

# Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/radiotherapy-3-times-a-day-vs-radiotherapy-daily-for-head-and-neck-cancer

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00021125

# Protocol serial number

E164/7 (CHARTWEL/CH03)

# Study information

#### Scientific Title

CHARTWEL - Continuous Hyperfractionated Accelerated Radiotherapy Week-End Less

## **Acronym**

**CHARTWEL** 

# **Study objectives**

The aim of the study is to compare CHARTWEL given over 16 days with conventional radical radiotherapy given daily over 6 weeks. Preventing recurrence of the disease is the primary outcome measure. Toxicity from the treatments, both early and late, disease-free and overall survival will also be assessed.

# 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**

Arm 1 - CHARTWEL radiotherapy. A total of 34 treatments of 1.5 Gy should be given three times per day, Monday to Friday in two consecutive weeks and the Monday and Tuesday of the following week (12 treatment days). An interval of at least 6 h must be arranged between the commencement of two treatments. A boost dose, which is recommended, of  $2 \times 1.5$  Gy should be given on the final treatment day. A total of 51 Gy + 3 Gy boost.

Arm 2 - Conventional radiotherapy. A total of 30 treatments of 2 Gy should be given once-a-day 5 days per week, over a period of 6 weeks (30 treatment days). A boost dose, which is recommended, of 2 x 2 Gy should be given on the last two treatment days. A total of 60 Gy + 4 Gy boost.

# Intervention Type

Other

#### Phase

**Not Specified** 

# Primary outcome(s)

The primary outcome measure, which will be used to evaluate the efficacy of the treatment regimens, will be time to local recurrence.

# Key secondary outcome(s))

- 1. Length of survival
- 2. Morbidity/toxicity (see form CH03/7)
- 3. Quality of life (EORTC QLQ H&N 35 Pro forma, CH03/QoL)

# Completion date

31/03/2005

# Eligibility

# Key inclusion criteria

- 1. Surgically resected and histologically proven squamous cell carcinoma of the head and neck area at high or intermediate risk of recurrence within the head and neck region
- 2. Elective surgery performed with the intention to cure
- 3. The patient must be treatable by a radiotherapy technique which can be used in both arms of the trial
- 4. The patient should have no other concurrent or previous malignant disease likely to interfere with protocol treatment or comparisons
- 5. Adequate follow-up possible
- 6. Written informed consent

# Participant type(s)

Patient

# Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

# Key exclusion criteria

- 1. Distant metastases beyond regional nodes in the neck.
- 2. Time from surgery to commencement of radiotherapy greater than 70 days.
- 3. Unable to tolerate protocol treatments

#### Date of first enrolment

01/04/2000

#### Date of final enrolment

31/03/2005

# Locations

## Countries of recruitment

United Kingdom

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

# Sponsor information

# Organisation

Medical Research Council (MRC) (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

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration