

CHARTWEL - Continuous Hyperfractionated Accelerated Radiotherapy Week-End Less

Submission date 08/11/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/11/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00021125

Secondary identifying numbers

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

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

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 x 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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2000

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

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**

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

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+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

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

IPD sharing plan summary

Not provided at time of registration