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CHARTWEL - Continuous Hyperfractionated Accelerated Radiotherapy Week-End Less

Submission date 08/11/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/11/2000	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/01/2019	**Condition category** Cancer	[_] Individual participant data [_] 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

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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

460

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
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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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