A trial comparing conventional fractionation with 'CHART' in the treatment of head and neck cancer

Submission date	Recruitment status	Prospectively registered
28/02/2001	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/02/2001	Completed	Results
Last Edited	Condition category	Individual participant data
29/10/2019	Cancer	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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

Secondary identifying numbers

CH02

Study information

Scientific Title

A trial comparing conventional fractionation with 'CHART' in the treatment of head and neck cancer

Study objectives

To compare the effectiveness of radical fractionated radiotherapy given daily over 6 weeks with CHART over 12 days, with respect to local tumour control, survival and morbidity

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

Conventional radiotherapy arm - 2 Gy, once daily five days a week over six weeks (large volume - 44 Gy in 22 fractions followed by small volume - 16 Gy in eight fractions)

CHART arm - 1.5 Gy, three time daily over 12 treatment days (large volume - 37.5 Gy in 25 fractions followed by small volume - 16.5 Gy in 11 fractions)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Local tumour control
- 2. Survival
- 3. Morbidity

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

Completion date

01/03/1995

Eligibility

Key inclusion criteria

1. Histologically proven squamous cell carcinoma of all grades at one of the following sites: Nasal sinuses, Nasopharynx, Oral cavity, Oropharynx, Hypopharynx, Carcinoma of the larynx 2. A radical course of external beam radiotherapy is the appropriate sole treatment

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

500

Key exclusion criteria

There should be no evidence of distant metastases beyond the regional nodes in the neck

Date of first enrolment

01/01/1990

Date of final enrolment

01/03/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre MRC Clinical Trials Unit London United Kingdom

Sponsor information

Organisation

NW1 2DA

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration