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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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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