ISRCTN86478952 https://doi.org/10.1186/ISRCTN86478952

A randomised two arm trial of modestly accelerated radiotherapy with synchronous cisplatinum chemotherapy versus conventional radiotherapy with synchronous cisplatinum chemotherapy in the treatment of head and neck squamous cell carcinoma: a pilot study

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 01/10/2012	**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

Protocol serial number

N0063116003

Study information

Scientific Title

Study objectives
To assess tolerability (absence of grade IV reactions) of synchronous chemotherapy and modestly accelerated radiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised/Prospective Pilot Phase I/II clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer: Head and neck

Interventions
Twelve eligible patients will receive accelerated radiotherapy (six fractions per week, over 5½ weeks to a total dose of 68 Gray). The extra fraction will be given on any day Monday to Friday (preferably Monday or Friday) and treatment will not normally be given at weekends. Cisplatinum chemotherapy will be given at a dose of 100 mg/m^2 on day one of chemotherapy and then again three weeks later. Acute and late radiation toxicities will be monitored using the Danish Head and Neck Cancer Study Group (DAHANCA) Acute and Late Morbidity Scoring Criteria.

Intervention Type
Other

Phase
Phase I/II

Primary outcome(s)
Primary end point: to assess tolerability of modestly accelerated radiotherapy with synchronous cisplatin chemotherapy

Key secondary outcome(s))

1. Disease-free survival
2. Normal tissue toxicity

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients with histologically proven squamous cell carcinoma of the oropharynx hypopharynx larynx or oral cavity (not nasopharynx/sinuses) and fully meet the criteria will be approached for consent. The study requires 12 patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
05/07/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Oncology
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Christie Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes