

A randomised two arm trial of modestly accelerated radiotherapy with synchronous cisplatin chemotherapy versus conventional radiotherapy with synchronous cisplatin 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
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/10/2012	Condition category Cancer	☐ Individual participant data

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

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

Primary study design

Interventional

Study design

Randomised/Prospective Pilot Phase I/II clinical trial

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. Cisplatin chemotherapy will be given at a dose of 100 mg/m² 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