

# 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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/10/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

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. Cisplatin chemotherapy will be given at a dose of 100 mg/m<sup>2</sup> 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?
<a href="#">Results article</a>	results	01/03/2011		Yes	No