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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Primary end point: to assess tolerability of modestly accelerated radiotherapy with synchronous cisplatin chemotherapy

Secondary outcome measures
1. Disease-free survival
2. Normal tissue toxicity

Overall study start date
05/07/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
12

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
England

United Kingdom

Study participating centre
Clinical Oncology
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Christie Hospital NHS Trust (UK)

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

Study outputs

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