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UKHAN1 - A Trial of Chemotherapy With Radiotherapy in the Treatment of Advanced Squamous Carcinoma of the Head and Neck

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 08/11/2012	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/trials-search/trial-radiotherapy-and-chemotherapy-for-head-and-neck-cancer-ukhan1

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002476

Secondary identifying numbers
UKCCCRUKHAN1

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
1. Group A: Radiotherapy alone.

2. Group B: Radiotherapy plus simultaneous chemotherapy (two courses during radiotherapy).

3.Group C: Radiotherapy plus subsequent chemotherapy (two courses to start 14 days and 28 days following radiotherapy).

4. Group D: Radiotherapy plus simultaneous and subsequent chemotherapy. (A total of four courses of chemotherapy, two simultaneous with radiotherapy treatment and two 14 days and 28 days following the completion of radiotherapy.)

Radiotherapy is given according to standard local practices. Suggested radiotherapy regimens include 60 Gy in 6 weeks or 45-55 Gy in 3-4 weeks. Recommended chemotherapy regimens are single agent methotrexate or combination chemotherapy with vincristine, bleomycin, methotrexate and 5-fluorouracil (VBMF). Patients in whom the primary tumour has been surgically excised are randomised to group A or group B only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/01/1990

Completion date
20/06/2000

Eligibility

Key inclusion criteria
1. Histological confirmation of squamous cell carcinoma
2. All stages, except T1N0
3. No occult primaries
4. No evidence of distant metastases
5. Fit and willing to receive any of the randomised treatment options

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

15/01/1990

Date of final enrolment
20/06/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
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Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No