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

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

Contact name

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Contact details

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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

Date of final enrolment 20/06/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University College Hospital London United Kingdom

Sponsor information

Organisation

NW1 2BU

Cancer Research UK (CRUK) (UK)

Sponsor details

PO Box 123 Lincoln's Inn Fields London United Kingdom WC2A 3PX +44 (0)207 317 5186 kate.law@cancer.org.uk

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