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A multicentre randomised phase III trial comparing Positron Emission Tomography - computed tomography guided watch and wait policy versus planned NECK dissection for the management of locally advanced (N2/N3) nodal metastases in patients with head and neck squamous cancer

Submission date
21/05/2007

Recruitment status
No longer recruiting

Registration date
12/06/2007

Overall study status
Completed

Last Edited
24/03/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-the-treatment-of-local-cancer-spread-in-head-and-neck-cancers

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00720070

Secondary identifying numbers
HTA 06/302/129; PET-NECK V1.0 5Feb07

Study information

Scientific Title
A multicentre randomised phase III trial comparing Positron Emission Tomography - computed tomography guided watch and wait policy versus planned NECK dissection for the management of locally advanced (N2/N3) nodal metastases in patients with head and neck squamous cancer

Acronym
PET-CT

Study objectives
Head and Neck Squamous Cell Carcinoma (HNSCC) is the sixth most common cancer worldwide with approximately 500,000 new cases/year. It poses a significant therapeutic problem as it has a high mortality and morbidity and survival rates have not considerably improved over the past two decades despite newer aggressive surgical and chemoradiotherapy (CRT) regimens.

CRT is the preferred first line of treatment for several types of HNSCC. For patients with large metastasis to the neck nodes, evidence for management is sparse. Current standard care is neck dissection either before/after CRT. There is debate regarding whether a neck dissection is needed or whether CRT alone is sufficient. Controversy continues mainly due to poor quality and contradictory evidence from prospective and retrospective case series for both management strategies. Furthermore the advent of newer, more accurate functional modalities for the detection of persistent disease, e.g., Positron Emission Tomography - Computed Tomography (PET-CT) scanning have further strengthened this debate.

Aim:
To test the hypotheses that a PET-CT guided watch and wait policy (experimental arm) is non-inferior to the current practice of planned neck dissection (control arm) when comparing overall and disease-specific survival in the management of advanced (N2 or N3) nodal metastasis in patients treated with CRT for their HNSCC primary. Recurrence, quality of life and cost effectiveness will be assessed as secondary outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee A, 09/05/2007, ref: 07/Q1604/35

Study design

Two-arm multi-centre randomised trial. Randomisation 1:1 with stratification (centre, chemotherapy schedule, N stage, T stage)

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Head and neck squamous cell carcinoma (HNSCC)

Interventions
CRT regimens:
All patients must receive concomitant CRT to be included in the trial. For each patient, the participating centre must specify the schedule that they will use. This regimen must be:
1. A CRT schedule that the centre uses in their normal, peer-reviewed practice
AND
2. The CRT schedule selected must be present in the list of approved trial schedules
The recommended standard radiotherapy schedule for the trial is radiotherapy doses of 65 to 70 Gy in 30 to 35 daily fractions of 2 Gy or more with at least two doses of concomitant three/four weekly intravenous cisplatin 75 to 100 mg/m^2 or carboplatin (4.5 to 5 AUC).

Control arm: planned pre-CRT neck dissections - neck dissections must be performed within two to four weeks of randomisation. The recommended surgical procedure is a modified radical neck dissection This involves removal of lymphatic structures in levels I-V, with preservation of one or more of the following: spinal accessory nerve, internal jugular vein, and sternocleidomastoid muscle.
Experimental arm: PET-CT scan

Both groups will be followed up for two years.

Intervention Type
Other

Phase
Phase III

Primary outcome measure

1. Overall survival, measured at at two years
2. Health economics (Quality Adjusted Life Years [QALYs]), measured at at two years

Secondary outcome measures
1. Disease-specific survival, measured at pre-treatment and 3, 6, 12 and 24 months post randomisation
2. Recurrence in the neck, measured at pre-treatment and 3, 6, 12 and 24 months post randomisation
3. Quality of life, measured at pre-treatment and 3, 6, 12 and 24 months post randomisation
4. Complication rates, measured at pre-treatment and 3, 6, 12 and 24 months post randomisation
5. Accuracy of PET-CT scanning for assessing the primary tumour

Overall study start date
01/04/2007

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Histological diagnosis of oropharyngeal, laryngeal, oral, hypopharyngeal or occult HNSCC
2. Clinical and CT/Magnetic Resonance Imaging (MRI) evidence of nodal metastases staged N2 (a, b or c) or N3
3. Indication to receive curative radical concurrent CRT for primary
4. Fitness for neck dissection surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
560

Key exclusion criteria
Current exclusion criteria as of 28/01/2011:
1. Patients undergoing resection for their primary tumour, e.g., resection of tonsil or base of tongue with flap reconstruction (diagnostic tonsillectomy not considered an exclusion criteria)
2. Patients with N1 nodal metastasis
3. Patients receiving neo-adjuvant chemoradiotherapy with no concomitant chemotherapy
4. Patients receiving adjuvant chemotherapy
5. Patients undergoing chemo +/- radiotherapy for palliative purposes
6. Patient undergoing radiotherapy alone (not optimal treatment for neck node disease)
7. Distant metastases to chest, liver, bones or other sites

8. Unfit for surgery or chemoradiotherapy
9. Previous treatment for head and neck squamous cell carcinoma
10. Patients have had another cancer diagnosis in the last five years (except basal cell carcinoma or carcinoma of the cervix in situ).
11. Pregnant patients
12. Patients under 18 years of age

Previous exclusion criteria:
10. Patients with occult nodal metastasis, i.e., large nodal metastasis but no proven primary site on clinical assessment

Date of first enrolment
01/04/2007

Date of final enrolment
20/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Sponsor information

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Sponsor type

Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

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
Not provided at time of registration

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	14/04/2016		Yes	No

Results article	results	01/04/2017		Yes	No
Plain English results			24/03/2022	No	Yes