ISRCTN74465582 https://doi.org/10.1186/ISRCTN74465582

Trial of Induction TPF therapy in Advanced head & Neck cancer

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 23/06/2020	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-tpf-chemotherapy-before-surgery-and-radiotherapy-for-locally-advanced-head-and-neck-cancer-titan

Study website
http://www.lctu.org.uk/trial/trial_info.asp?id=68&tgcode=2&menuid=30

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-023195-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10000

Study information

Scientific Title
Randomised controlled open-label trial of TPF (taxane cisplatin 5-fluorouracil) induction chemotherapy in the surgical management of locally advanced head and neck cancer

Acronym
TITAN

Study objectives
This is a trial of treatment intensification in a high-risk population of potentially curable patients. Induction chemotherapy is a significant recent advance in the management of locally advanced squamous cell carcinoma of the head and neck (SCCHN), although its use in combination with surgery and postoperative radiotherapy (PORT) is under-researched. Induction chemotherapy (ICT) offers the potential for better delivery of drugs to "treatment naïve" tumours with an intact blood supply and, at the same time, provides maximal treatment to eradicate micro-metastasis, with the prospect of both better local and local systemic control of disease.

Thus the rationale is to study the effects of intensification of treatment using induction TPF in locally advanced SCCHN in those anatomical sites treated by primary surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 11/04/2011, ref: 11/NW/0149

Study design
Randomised, interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not provided at time of registration

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

Interventions
Patients will be randomised in a 1:1 ratio across 2 arms

Arm A: surgery and post operative conformal radiation therapy (CRT) (PO(C)RT)
Conventional treatment for the stage and site of disease is performed as per the original (pre-randomisation) imaging, examination under anaesthetic and clinical findings.

Arm B: Induction Chemotherapy
Patients will recieve 3 cycles of induction chemotherapy at 21 days intervals, prior to recieving surgery and PO(C)RT

To be followed up at 60 month(s)

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Taxane, cisplatin, 5-fluorouracil

Primary outcome measure
Feasibility of recruitment into the TITAN trial (specifically the number of participants)

Secondary outcome measures
1. Randomisation: screening ratio
2. The percentage of patients in the TPF arm who complete the full course of treatment

Overall study start date
01/09/2011

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Age >18 years
2. Histopathological diagnosis of head and neck squamous cell carcinoma
3. Tumour (T) stage in one of the following site categories:
3.1. Lip/ Oral cavity: stage T3 or T4a (and >=4cm in largest dimension)
3.2. Paranasal /nasal: stage T4a
3.3. Larynx: stage T4a
3.4. Hypopharynx: stage T3 or T4a
3.5. Cervical oesophagus: stage T3 or T4a
3.6. Oropharynx: stage T3 or T4a and HPV-ve
4. Any lymph node (N) stage
5. No metastases (M0)
6. An multidisciplinary team (MDT) decision to offer surgery as primary modality of treatment

7. World Health Organisation (WHO) performance status 0 or 1
8. Resectable by conventional criteria in both primary site and any cervical lymph node involvement
9. Male or female paticipants
10. Lower age limit: 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 50

Total final enrolment
7

Key exclusion criteria
1. Those tumours staged to T4a on the basis of early mandibular invasion alone, i.e. <4cm in the maximum dimension
2. Unresectable disease on clinical staging (including imaging) of primary tumour or cervical metastasis
3. Distant metastases (note: positron emission tomography - computed tomography [PET-CT] is necessary investigation for all patients entering trial - as such additional CT chest will usually not be required to exclude pulmonary or hepatic metastases)
4. Nasopharynx site
5. Human papillomavirus (HPV) - positive oropharyngeal cancer (OPC)
6. Pregnancy or lactation
7. Patients with haemoglobin of <10g/dl
8. Patients with neutrophil counts of <1.5 x 109/l.
9. Patients with thrombocyte counts of <100 x 109/l.
10. Patients with significant hepatic impairment (Bilirubin >1.5x upper limit of normal range; ALT >2.5x upper limit of normal range; ALP >5x upper limit of normal range)
11. Patients with significant renal impairment (For the purpose of the study, significant renal impairment is classed as GFR <50ml/min>. However, sites may use their local policy if a higher threshold is dictated.)
12. Patients who lack mental capacity to give informed consent
13. Patients whose co morbidities or concomitant medications otherwise preclude TPF chemotherapy
14. All men or women of reproductive potential, unless using at least two contraceptive precautions, one of which must be a condom

Date of first enrolment
01/09/2011

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool Cancer Research Centre
Liverpool
United Kingdom
L3 9TA

Sponsor information

Organisation
Aintree University Hospitals NHS Foundation Trust (UK)

Sponsor details
Aintree University Hospitals
Fazakerley Hospital
Lower Lane
Liverpool
England
United Kingdom
L9 7AL

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02h67vt10

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?
Basic results			23/06/2020	No	No
HRA research summary			28/06/2023	No	No