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Accelerated hypofractionation, Chemotherapy, Intensity Modulation and Evaluation of Dose Escalation in Oropharyngeal cancer

Submission date 09/02/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/05/2012	**Overall study status** Completed	
Last Edited 26/02/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-increased-dose-intensity-modulated-radiotherapy-treat-head-neck-cancer-archimedes-op

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HN2001

Study information

Scientific Title
Accelerated hypofractionation, Chemotherapy, Intensity Modulation and Evaluation of Dose Escalation in Oropharyngeal cancer: a non randomised study

Acronym
ArChIMEDEs-Op

Study objectives
To determine whether it is safe and feasible to deliver a 5 week schedule of dose escalated intensity modulated chemoradiotherapy for poor prognosis patients with Human Papillomavirus (HPV) negative and P16 negative locally advanced squamous carcinoma of the oropharynx (SCCOP) in the context of a feasibility study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee, South Birmingham, ref. 12/WM/0112.

Study design
Single arm single centre non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non 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
Locally advanced squamous carcinoma of the oropharynx

Interventions
Patients entered into the study will receive intensity modulated chemoradiotherapy (IMRT), 64Gy in 25F for 5 weeks. Chemotherapy (cisplatin) will also be given as standard practice once in the 1st week and once in the last week of radiotherapy.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cisplatin

Primary outcome measure
Full dose radiotherapy received as planned and the absence of consequential damage defined by the absence of Grade 3 mucositis at 3 months

Secondary outcome measures
1. Duration of Grade 3 mucositis: defined as the number of days of Grade 3 mucositis scored using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3
2. Incidence of acute Grade 4 toxicity defined according to the NCI CTCAE version 4
3. Incidence of ≥ Grade 3 late toxicity defined according to RTOG (see appendix 2) and CTCAE version 4 scoring systems
4. Complete response rate at 3 months defined as no clinically visible (including endoscopic evaluation), palpable or measurable disease on imaging OR the absence of residual tumour on directed biopsy/neck dissection. The primary tumour and regional lymph nodes will be considered separately
5. Two year local control defined as no re-appearance of tumour within primary site (including immediately adjoining anatomical sites) or regional lymph nodes after complete response
6. Two year disease free survival defined in whole days, as the time from entry into the study until death from any cause. Patients will be censored at the date last seen alive. All patients will be followed up for at least 5-years
7. Two year overall survival defined in whole days as the time from entry into the study until death from any cause. Patients will be censored at the date last seen alive. All patients will be followed up for at least 5-years
8. Incidence of feeding tube dependency at one year defined by the patient requiring supplementation of nutrition by a feeding tube

Overall study start date
03/09/2012

Completion date
02/12/2019

Eligibility

Key inclusion criteria
1. Histologically proven, P16 negative SCCOP deemed suitable for radical primary chemoradiotherapy with curative intent requiring bilateral neck irradiation. Neoadjuvant chemotherapy and pre or post chemoradiation neck dissections are permitted
2. Only patients requiring bilateral radiotherapy
3. Age ≥18 and <75 years
4. World Health Organisation (WHO) performance status 0 or 1

5. Adequate bone marrow: absolute neutrophil count > 1,800 cells/mm3, platelets > 100,000 cells /mm3, haemoglobin > 8.0 g/dl
6. Creatinine clearance > 50 ml/minute
7. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Prior invasive malignancy (except basal cell carcinoma and cervical intraepithelial neoplasia) within last 3 years
2. Prior radiotherapy to the head and neck region
3. Pregnancy and/or lactation
4. Reproductive capability agreement to use contraceptive
5. Contraindications to cisplatin chemotherapy including active vascular disease (e.g. myocardial within last 6 months, angina and symptomatic peripheral vascular disease)
6. Non curative intent
7. Non squamous cell carcinoma histology
8. Nasophaynx, larynx, hypopharynx, salivary gland or sino-nasal primary site
9. Other physical or psychiatric disorder that may interfere with subject compliance, adequate informed consent, follow up or determine the causality of adverse events
10. Suitable for unilateral radiotherapy

Date of first enrolment
02/11/2012

Date of final enrolment
22/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

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University/education

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ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Charity

Funder Name
Queen Elizabeth Hospital Birmingham Charities (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	01/06/2018		Yes	No
Plain English results			26/02/2020	No	Yes