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Improving treatment selection for head and neck cancers and dysplasia

Submission date	**Recruitment status**	[X] Prospectively registered
02/02/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/02/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/12/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Head and neck cancer (HNC) and its treatments have considerable quality of life effects and therapeutic, rehabilitative and social costs for patient and NHS. Survival is relatively poor and has not improved a lot despite a choice of new treatments. Therefore there is a need to improve health outcomes.One of the main reasons for the problems above is that tumours have different biological characteristics. There is a need for better methods of prognostication and treatment selection taking into account the biological characteristics of disease. Recently there have been several publications showing that certain immunohistological biomarkers strongly predict response to chemoradiotherapy and significantly enhanced survival in cohorts of patients that have been recruited during RCTs. These include HPV, p16, EGFR and Bcl-2, CA-9. These studies have involved single or at most two markers at a time, and have not incorporated other known established prognostic factors such as stage of disease or smoking status. Further more these findings have not been validated independently on other cohorts. The aim of the study is to identify markers that can be used to determine whether patients with oropharyngeal cancer will respond to certain treatments before they receive their treatments. This will mean that patients will receive the most appropriate treatment and this would likely result in the best outcome for them.

Who can participate?
Any patient who has had treatment for oropharyngeal cancer

What does the study involve?
The samples and information of the treatment for that patient will be obtained from their base hospital. The samples will then be tested for the biomarkers that are being studied. The results will then be analysed to see if the biomarkers can predict the response from the treatment that the patient had.

What are the possible benefits and risks of participating?
Since this is a retrospective study that looks at what treatments patients already have, then there is no risk to patients. The benefits are that the results may help future patients.

Where is the study run from?
The study is run from the Institute of Head and Neck Studies and Education at the University Hospitals Coventry.

When is study starting and how long is it expected to run for?
The study starts in May 2012 and is running for two years.

Who is funding the study?
Cancer Research UK

Who is the main contact?
Gemma Jones
Gemma.Jones@uhcw.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Gemma Jones

Contact details
University Hospitals Coventry & Warwick
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
+44 2476 964 000
Gemma.Jones@uhcw.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11317

Study information

Scientific Title
Improving treatment selection using PREDICtive and prognostic classifiers of Treatment Response for Head and Neck Cancers and dysplasia

Acronym
PREDICTR-HNC

Study objectives
Aims: The project will validate the use of molecular biomarkers to better select the management of individual patients with oropharyngeal cancer. This should improve survival and quality of care because patients will receive the treatments most likely to help them and avoid the unnecessary toxicity, morbidity and cost of potentially ineffective treatment.

Objectives: To develop and validate biomarker prognostic (PC) and treatment response classifiers (TRC) to select those patients with oropharyngeal cancers most likely to respond to chemoradiotherapy or surgery. A PC and TRC are mathematical functions that translates clinical factors and biomarker values into a set of prognostic and predictive outcomes, which select and stratify patients for treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Covenry & Warwickshire, 14 November 2011 ref: 10/H1210/9

Study design
Observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Head and neck cancer

Interventions
The outcome data and samples of patients with oropharyngeal cancer receiving either chemoradiotherapy or surgery plus or minus chemo-radiotherapy are collated from each centre. Samples are then analysed using the selected biomarkers. Complex bioinformatics analysis is then undertaken to look at the prognostic and predictive effects of selected biomarkers.

Followed up for 36 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Survival measured at the end of the study

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2012

Completion date
21/04/2014

Eligibility

Key inclusion criteria
1. Oropharyngeal (tonsil or base of tongue) squamous carcinoma
2. Has a minimum 3 year follow up or to recurrence or death if occured before 3 years
3. Treatment by chemoradiotherapy or by surgery +/- post operative RT or chemoradiotherapy
4. Has clinical data including TNM staging available
5. Formalin fixed, paraffin embedded tissue block available
6. Male & female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 1400

Key exclusion criteria
1. No follow-up data
2. Not of stated primary site

Date of first enrolment
01/05/2012

Date of final enrolment
21/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry & Warwick (UK)

Sponsor details
University Suite
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/025n38288

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