

Oral cancer: molecular, cellular and immunological mechanisms

Submission date 30/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/06/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-study-to-learn-more-about-causes-mouth-cancer>

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

Secondary identifying numbers
8130

Study information

Scientific Title

Investigation of the molecular mechanisms promoting oral cancer development and progression

Study objectives

Oral cancer (OSCC) is the 8th most common cancer worldwide, representing about 4% of all malignancies. In the UK, the incidence has increased dramatically over the last 20 years, particularly in young non-smokers, with around 5,000 new cases each year. Compared with many cancers, OSCC remains a relatively understudied disease. And despite advances in surgery and radiotherapy, which remain the standard treatment options, the mortality rate has remained unchanged for decades, with a 5-year survival rate of around 50%.

Oral cancer may be preceded by a premalignant, histologically dysplastic lesion, usually presenting clinically as a white or red patch in the mouth. However, only around 10 - 15% of patients diagnosed with oral dysplasia will develop oral cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee, 11/01/2010, ref: 09/H0501/90

Study design

Non-randomised observational clinical laboratory study

Primary study design

Observational

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

Topic: National Cancer Research Network; Subtopic: Head and Neck Cancer; Disease: Head and Neck

Interventions

1. Surgical biopsy
2. Venesection

Study entry: registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

To gain an increased understanding of the cellular and molecular biology of oral/oropharyngeal cancer. This will involve identifying biomarkers which may predict patient prognosis and/or response to treatment.

Secondary outcome measures

No secondary outcome measures

Overall study start date

05/04/2010

Completion date

20/03/2015

Eligibility

Key inclusion criteria

1. Clinical suspicion of premalignant oral/oropharyngeal lesion and/or condition
2. Clinical and histopathologic diagnosis of oral/oropharyngeal cancer
3. Male and female, lower age limit of 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 500

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

05/04/2010

Date of final enrolment

20/03/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cancer Sciences Building

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

Sponsor type

Hospital/treatment centre

Website

<http://www.soton.ac.uk/>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Charity

Funder Name

British Association of Oral and Maxillofacial Surgeons (UK)

Funder Name

Cancer Research UK (CRUK) (UK) (ref: 507862102)

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

Funder Name

The Health Foundation (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