

# Oral cancer: molecular, cellular and immunological mechanisms

<b>Submission date</b> 30/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/06/2020	<b>Condition category</b> 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