

# Is risk prediction possible in head and neck free flap surgery?

<b>Submission date</b> 28/03/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/05/2015	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Being able to predict the risk of complications or death associated with surgery is becoming more important because it helps inform patients about the possible outcomes of their operation. It also provides a way to assess how successful a surgeon or hospital unit is. The Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (POSSUM) is widely used to calculate risk in general surgery. However, there is currently no way to calculate the risk of Head and Neck Free Flap Surgery (HNFFS) because POSSUM scoring in HNFFS is thought to be not very accurate. This means that doctors cannot provide patients with a personalised percentage risk of complications or death before they have their HNFFS. This study aims to formulate an equation that will enable researchers to develop such a risk calculation.

### Who can participate?

All patients in South Wales undergoing HNFFS for cancer.

### What does the study involve?

This study only involves data collection and does not alter a patient's treatment plan in anyway. Data is collected at three points: before surgery, on the day of/during surgery and throughout the hospital stay. Participants are asked to complete various questionnaires related to lifestyle and health history.

### What are the possible benefits and risks of participating?

The results of the study will not benefit participants directly. However, it will allow future head and neck cancer patients to be given a percentage risk calculation of possible complications and death related to their surgery which might assist in their decision making. There are no side effects or risks to patients.

### Where is the study run from?

1. Morriston Hospital Wales (UK)
2. University Hospital Wales (UK)
3. Royal Gwent Hospital Wales (UK)

When is the study starting and how long is it expected to run for?  
August 2015 to August 2017

Who is funding the study?  
Investigator initiated and funded (UK)

Who is the main contact?  
Mr N Scott (UK)  
NeilThomas.Scott@Wales.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Neil Scott

**Contact details**  
Department of Oral and Maxillofacial Surgery  
Morriston Hospital  
Swansea  
United Kingdom  
SA6 6NL

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (POSSUM): a tool to predict morbidity & mortality in Head & Neck Free Flap Surgery

**Acronym**  
POSSUM in HNFFS

**Study objectives**  
Risk prediction (morbidity and mortality) is possible in Head and Neck Free Flap Surgery using an adapted Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (POSSUM) risk assessment calculation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Wales REC, 20/04/2015, ref: 15/WA/0136.

**Study design**

Prospective cohort

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format . Please use the contact details to request a patient information sheet.

**Health condition(s) or problem(s) studied**

Risk prediction in patients undergoing free flap reconstruction surgery following oral cancer surgical resection.

**Interventions**

1. Pre-operative data: age, smoking history; alcohol history; Performance Status questionnaire; Adult Co-morbidity Evaluation (ACE-27); previous surgery to head and neck; previous radiotherapy to head and neck; tumour stage and nodal status.
2. Peri-operative data: duration of surgery; type of free flap; blood loss; tracheostomy performed; ischaemic time of free flap.
3. Post-operative data: all patient complications are recorded.

**Intervention Type**

Other

**Primary outcome measure**

30 day morbidity in head and neck free flap surgery.

**Secondary outcome measures**

No secondary outcome measures.

**Overall study start date**

01/10/2014

**Completion date**

04/08/2017

## Eligibility

### Key inclusion criteria

Patients undergoing head and neck free flap surgical reconstruction for oral cancer.

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

300

### Key exclusion criteria

Patients NOT undergoing head and neck free flap surgical reconstruction for oral cancer.

### Date of first enrolment

03/08/2015

### Date of final enrolment

04/08/2017

## Locations

### Countries of recruitment

United Kingdom

Wales

### Study participating centre

**Morrison Hospital**

Morrison Hospital

ABMU Health Board

Heol Maes Eglwys

Swansea

United Kingdom

SA6 6NL

### Study participating centre

**University Hospital Wales**

Heath Park

Cardiff

United Kingdom

CF14 4XW

**Study participating centre****Royal Gwent Hospital**

Cardiff Road

Newport

United Kingdom

NP20 2UB

## Sponsor information

**Organisation**

Morrison Hospital

**Sponsor details**

Research and Development Department

ABMU Health Board

Swansea

Wales

United Kingdom

SA6 6NL

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01p830915>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

The study will be written up as a full length article and submitted to the British Journal of Oral and Maxillofacial Surgery or Head and Neck. It will also be submitted to appropriate conferences for oral presentation.

## Intention to publish date

01/01/2018

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No