

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

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

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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

Protocol serial number

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

Study type(s)

Other

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(s)

30 day morbidity in head and neck free flap surgery.

Key secondary outcome(s))

No secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Morriston Hospital

Morriston 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
Morriston Hospital

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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?
HRA research summary		28/06/2023	No	No	
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes