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

Submission date 28/03/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/05/2015	**Overall study status** Completed	
Last Edited 01/05/2015	**Condition category** Surgery	

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
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Additional identifiers

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.

Primary study design
Observational

Study design
Prospective cohort

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
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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