

# Remote ischaemic preconditioning to reduce myocardial complications following head and neck cancer surgery

<b>Submission date</b> 07/07/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/04/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Patrick Doyle

**Contact details**  
Department of Anaesthesia  
Imperial College Healthcare NHS Trust  
Charing Cross Hospital  
London  
United Kingdom  
W6 8RF  
-  
patrick.doyle@imperial.nhs.uk

## Additional identifiers

**Protocol serial number**  
10/H0801/2

## Study information

**Scientific Title**

A prospective double-blind randomised controlled trial of the impact of remote-organ ischaemic preconditioning on perioperative myocardial morbidity and postoperative complications in head and neck surgery: Myocardial Event Reduction with Ischaemic-preconditioning Therapy (MERIT)

## **Acronym**

MERIT

## **Study objectives**

Does remote ischaemic preconditioning reduce the incidence of myocardial damage associated with major head and neck surgery? As a secondary hypothesis, does remote ischaemic preconditioning reduce the degree of post-operative inflammation, the number and severity of post-operative complications, length of critical care stay, and the overall duration of hospitalisation?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Royal Marsden Research Ethics Committee, 02/02/2010, ref: 10/H0801/2

## **Primary study design**

Interventional

## **Study design**

Double-blind randomised controlled trial

## **Study type(s)**

Treatment

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

Squamous cell carcinoma of the upper aerodigestive tract

## **Interventions**

The intervention group will receive remote ischaemic preconditioning which will be achieved immediately after induction of anaesthesia using an orthopaedic lower limb tourniquet inflated to 50 mmHg above the systolic pressure for two cycles of five minutes, interleaved with a single seven-minute period of reperfusion.

The control group will not have remote ischaemic preconditioning; they will have a lower limb tourniquet placed around their leg but this will not be inflated.

The duration of treatment is 20 minutes and the follow-up is six months.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Incidence of myocardial injury following head and neck surgery, as measured by the level of cardiac troponin enzyme at days 1, 3 and 7 after the operation.

## **Key secondary outcome(s)**

1. The rate of rise of C-reactive protein levels in the post-operative period (the inflammatory gradient)
2. Incidence and severity of post-operative complications as graded on a validated complications grading system
3. Length of stay in the Intensive Care, High-dependency and ward
4. Patient weight and swallowing status during follow-up
5. One-year MACE (Major Acute Cardiovascular Event) rate

**Completion date**

05/08/2012

## Eligibility

**Key inclusion criteria**

1. Patients aged under 90 years, either sex
2. Squamous cell carcinoma of the upper aerodigestive tract (head and neck cancer)
3. Undergoing excision of the primary site tumour and removal of cervical lymph nodes as part of the management of their condition

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients over 90 years of age
2. Patients unable to give informed consent
3. Patients unfit to undergo general anaesthesia
4. Patients undergoing only neck dissection surgery
5. Patients with non-squamous cell carcinoma pathology
6. Patients undergoing excision of tumours of the skull base
7. Diabetic patients taking sulphonylurea medications
8. Patients taking nicorandil
9. Patients undergoing trans-oral laser resection of tumours
10. Patients with a previous history of deep-vein thrombosis or pulmonary embolism
11. Patients with known peripheral vascular disease who have an Ankle-Brachial Pressure Index less than 0.7)

**Date of first enrolment**

05/08/2010

**Date of final enrolment**

05/08/2012

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Charing Cross Hospital**

London

United Kingdom

W6 8RF

# Sponsor information

## Organisation

Imperial College Healthcare NHS Trust (UK)

## ROR

<https://ror.org/056ffv270>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Imperial College Healthcare NHS Trust (UK)

## Alternative Name(s)

Imperial NHS, imperialnhs, Imperial College Healthcare NHS Trust | London

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration