

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

Submission date 07/07/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/04/2018	Condition category 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

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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

Study design

Double-blind randomised controlled trial

Primary study design

Interventional

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