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

Submission date 07/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/07/2010	**Overall study status** Completed	
Last Edited 25/04/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 torniquet 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 measure
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.

Secondary outcome measures
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

Overall study start date
05/08/2010

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

Age group
Adult

Sex
Both

Target number of participants
92

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
England

United Kingdom

Study participating centre
Charing Cross Hospital
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College Healthcare NHS Trust (UK)

Sponsor details
c/o Michelle Quaye
The Joint Research Office
Hammersmith Hospital
Du Cane Road
London
England

United Kingdom
W14 0HS

Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration