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The role and modulation of the adaptive immune response in human limb ischaemia reperfusion injury by ischaemic preconditioning

Submission date 09/08/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/08/2008	**Overall study status** Completed	
Last Edited 28/08/2008	**Condition category** Surgery	

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
N/A

Study information

Scientific Title

Study objectives
That local ischaemic preconditioning will alter bedside physiological parameters and systemic T cell activation, cytokine production and release in otherwise healthy patients undergoing lower limb surgery under tourniquet control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethical Committee at University College Hospital Galway. Date of approval: 15 /12/2005 (ref: 48/05)

Study design
Prospective, single-centre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Reperfusion injury

Interventions
Consecutive patients undergoing anterior cruciate ligament repair were randomised to surgery alone or surgery preceded by three 5 minute cycles of local ischaemic preconditioning to the operative limb within 1 hour of surgery. Surgery to include 1 hour of limb ischaemia. An operative tourniquet was placed on the upper thigh and the limb was exsanguinated using a Rhys Davies air sleeve. Tourniquet pressure was set at 100 mmHg above systolic brachial blood pressure. Ischaemia was verified by arterial doppler distal to the tourniquet. Systemic venous blood was collected on admission, at 4 and 24 hours post reperfusion (post-operatively).

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
1. Change in perioperative systemic mean arterial pressure and heart rate
2. Alterations in systemic T cell subsets as evaluated by flow cytometry, assessed on the systemic venous blood collected on admission, at 4 and 24 hours post reperfusion (post-operatively)
3. Alterations in systemic cytokine levels (Interleukin-2 [IL2] and interferon, gamma [IFNg]), assessed on the systemic venous blood collected on admission, at 4 and 24 hours post reperfusion (post-operatively)
4. Co-culture production of IL-2, IL-4, IL-10 and IFNg, assessed using the samples taken from patients 4 hours post reperfusion. Controls were taken from healthy volunteers.
5. Co-culture alteration in T cell subsets, assessed using the samples taken from patients 4 hours post reperfusion. Controls were taken from healthy volunteers.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2006

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Patients (both males and females) diagnosed with anterior cruciate ligament rupture by magnetic resonance imaging (MRI) or arthroscopy and undergoing patellar tendon graft reconstruction under tourniquet control.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Age under 18 or over 45
2. Having smoked in the preceding 3 months
3. Diagnosis of systemic auto-immune condition (e.g., thyroxicosis, inflammatory bowel/ coeliac disease, rheumatoid arthritis, systemic lupus erythematosus [SLE])
4. Diabetes
5. Concurrent medical condition

6. Pregnancy
7. Medications other than simple analgesics and non-steroidal anti-inflammatory drugs (NSAID)

Date of first enrolment
01/07/2006

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Surgery
Galway
Ireland
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Sponsor information

Organisation
National University of Ireland Galway (Ireland)

Sponsor details
c/o Prof Michael Kerin
University College Hospital
Department of Surgery
Clinical Science Institute
Galway
Ireland
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Sponsor type
University/education

Website
http://www.nuigalway.ie/surgery

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
National University of Ireland Galway, Department of Surgery (Ireland)

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