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

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

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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

## Study type(s)
Prevention

## 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(s)
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.

### Key secondary outcome(s))
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
-

# Sponsor information

**Organisation**
National University of Ireland Galway (Ireland)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration