

# Effects of ethanol on injury-induced changes in cardiovascular control

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2020	<b>Condition category</b> Circulatory System	<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 D Thomas

**Contact details**  
University Hospital of North Durham  
North Road  
Durham  
United Kingdom  
DH1 5TW

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0521099246

## Study information

**Scientific Title**

## Effects of ethanol on injury-induced changes in cardiovascular control

### Study objectives

The object of the proposed study is to test the following hypotheses

1. Simulated musculo-skeletal injury in normal volunteers will:
  - 1.1. Reduce resting vagal tone to the heart, assessed using heart rate variability
  - 1.2. Attenuate the baroreflex, assessed using the Valsalva ratio
2. The effects of simulated injury listed above will be enhanced in the presence of ethanol (100-200 mg% blood level).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised crossover trial

### Primary study design

Interventional

### Secondary study design

Randomised cross over trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

Cardiovascular: Heart rate

### Interventions

Each subject will act as his/her own control. Each volunteer will be subjected to the following assessments:

1. Measurements of heart rate, blood pressure and respiratory rate
2. Heart rate variability in the presence and absence of a cold stimulus to the face (normal and enhanced vagal tone to the heart respectively)
3. Valsalva ratio (baroreflex)

These assessments will be made before and during a 20 minute period of limb ischaemia induced by the bilateral application of pneumatic thigh cuffs (to simulate musculo skeletal injury). This will provide pre-injury (control) data followed by the effects of simulated injury. The entire sequence will be performed, on separate occasions on the same subjects, in the presence and absence of ethanol (vodka in orange juice given orally to obtain a blood alcohol level of 100-200 mg%).

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

The aim of the project is to determine in volunteers whether simulated injury alters the vagal activity to the heart, attenuates the baroreflex and whether these effects are enhanced by clinically relevant levels of ethanol in the blood.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2001

**Completion date**

30/06/2004

## Eligibility

**Key inclusion criteria**

Healthy male volunteers

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Male

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/06/2001

**Date of final enrolment**

30/06/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**University Hospital of North Durham**  
Durham  
United Kingdom  
DH1 5TW

## **Sponsor information**

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
County Durham and Darlington Acute Hospitals NHS Trust (North) (UK)

## **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