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Effects of ethanol on injury-induced changes in cardiovascular control

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 25/03/2020	**Condition category** Circulatory System	[ ] Individual participant data [ ] 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

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