

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised crossover trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2004

Eligibility

Key inclusion criteria

Healthy male volunteers

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

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

United Kingdom

England

Study participating centre

University Hospital of North Durham

Durham

United Kingdom

DH1 5TW

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration