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Exercise and vitamin C supplementation in type one diabetes mellitus

Submission date	Recruitment status
16/04/2008	No longer recruiting
Registration date	**Overall study status**
12/06/2008	Completed
Last Edited	**Condition category**
27/03/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Molecular detection of exercise-induced free radicals following ascorbate prophylaxis in type one diabetes mellitus: a randomised controlled trial

Study objectives
Consistent with the human literature, we hypothesise that compared to healthy controls:
1. Exercise would compound basal oxidative stress in type one diabetics, and
2. Ascorbic acid would provide effective prophylaxis

A randomised, double-blind, placebo-controlled experimental design incorporating an electron paramagnetic resonance (EPR) spin-trapping technique combined with a comprehensive assessment of lipid peroxidation and non-enzymatic antioxidants will be employed to test these hypotheses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from The Bro Taf (Wales) Research Ethics Committee on the 18th December 1996 (ref: 96/1649).

Study design
A balanced single-centre randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type one diabetes mellitus

Interventions
Subjects were randomised to receive:
1. 1 g ascorbic acid two hours prior to exercise
2. Placebo two hours prior to exercise

Supplementation took place once only for both treatment groups, and the follow up was conducted immediately post-exercise and 24 hours later via telephone.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ascorbic acid

Primary outcome measure
Free radical species in human blood, measured before supplementation, two hours after supplementation (before exercise) and immediately after exercise.

Secondary outcome measures
Blood biochemical markers such as lipid hydroperoxides, vitamin C and vitamin E, measured before supplementation, two hours after supplementation (before exercise) and immediately after exercise.

Overall study start date
01/01/2001

Completion date
01/06/2001

Eligibility

Key inclusion criteria
Diabetic volunteers were recruited from the adult diabetic clinic at the University Hospital of Wales, based on the following inclusion criteria:
1. Males aged 18 - 30 years
2. Glycosylated haemoglobin (HbA1c) of between 7 - 10%
3. Microalbuminuria negative
4. No underlying vascular complications

Non-diabetic control subjects were recruited from the student population of the University of Glamorgan, based on the following inclusion criteria:
1. Matched for age
2. Matched for fitness
3. No metabolic or circulatory medical condition
4. Had no family history of diabetes as confirmed via interview and medical history questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
12 male type one diabetic patients; 14 apparently healthy male volunteers

Key exclusion criteria
1. Cardiovascular disease
2. Hypertension
3. Any other known cardiac complication

Date of first enrolment
01/01/2001

Date of final enrolment
01/06/2001

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Ulster
Newtownabbey
United Kingdom
BT37 OQB

Sponsor information

Organisation
University of Glamorgan (UK)

Sponsor details
Pontypridd
Cardiff
Wales
United Kingdom
CF37 1DL

Sponsor type
University/education

Website
http://www.glam.ac.uk/

ROR
https://ror.org/02mzn7s88

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Glamorgan (UK)

Funder Name
University Hospital of Wales (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008		Yes	No