

# Exercise and vitamin C supplementation in type one diabetes mellitus

<b>Submission date</b> 16/04/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/03/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**Protocol serial number**  
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

### **Study type(s)**

Screening

### **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(s)**

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

### **Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**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)

### 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

### 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?
<a href="#">Results article</a>	results	01/11/2008		Yes	No