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# Reversibility of cerebrovascular endothelial dysfunction in patients with diabetes

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| **Submission date**<br>08/09/2005 | **Recruitment status**<br>No longer recruiting |
| **Registration date**<br>27/10/2005 | **Overall study status**<br>Completed |
| **Last Edited**<br>23/08/2013 | **Condition category**<br>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

**Contact name**
Dr Matthew Walters

**Contact details**
Department of Medicine & Therapeutics
Western Infirmary
44 Church Street
Glasgow
United Kingdom
G11 6NT
+44 (0)141 211 2821
gcl203@clinmed.gla.ac.uk

## Additional identifiers

**EudraCT/CTIS number**
2005-001670-27

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

### Scientific Title

### Study objectives
The purpose of the study is to investigate the effect of both losartan and atenolol upon impaired cerebrovascular reactivity in diabetic patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

### Interventions
Patients will undergo baseline assessment of cerebrovascular reactivity, mean flow velocity (MFV) in the middle cerebral artery (MCA) will be measured using transcranial Doppler. Each subject will then receive an intravenous infusion of L-NMMA after which MFV will be measured as before. Mean flow velocity in the internal carotid artery and peripheral arterial stiffness using Sphygmocor will also be assessed pre- and post-infusion for comparison. Patients then receive a supply of either losartan or atenolol tablets for 2 weeks after which they will undergo the same protocol as before. A 2-week washout period of no medication will follow, then the protocol repeated with the alternate tablet.

### Intervention Type
Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)
Losartan and atenolol

### Primary outcome measure
The aim of the study is to investigate the potential reversibility of the observed impairment of endothelial function.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/07/2005

### Completion date
01/07/2006

## Eligibility

### Key inclusion criteria
1. Type II diabetes <5 years duration
2. Age >40 years
3. Normal full Bruce protocol exercise tolerance test

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
18

### Key exclusion criteria
1. >70% internal carotid artery (ICA) stenosis
2. Significant comorbidity
3. Contra-indication to administration of angiotensin II receptor blocker (ARB)/angiotensin converting enzyme (ACE)-1/beta-blocker
4. Ongoing treatment with ARB/ACE1/beta-blocker unless can be withdrawn 4 weeks prior to randomisation

### Date of first enrolment
01/07/2005

### Date of final enrolment
01/07/2006

# Locations

**Countries of recruitment**
Scotland

United Kingdom

**Study participating centre**
**Department of Medicine & Therapeutics**
Glasgow
United Kingdom
G11 6NT

# Sponsor information

**Organisation**
University of Glasgow (UK)

**Sponsor details**
University Avenue
Glasgow
Scotland
United Kingdom
G11 6NT
+44 (0)141 339 8855
pcn1w@clinmed.gla.ac.uk

**Sponsor type**
University/education

**ROR**
https://ror.org/00vtgdb53

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Glasgow (UK)

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
United Kingdom

## 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 | 01/01/2009 | | Yes | No |