

# Reversibility of cerebrovascular endothelial dysfunction in patients with diabetes

<b>Submission date</b> 08/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/08/2013	<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

**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

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+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?
<a href="#">Results article</a>	results	01/01/2009		Yes	No