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Reversibility of cerebrovascular endothelial dysfunction in patients with diabetes

Submission date	Recruitment status	[ ] Prospectively registered
08/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/08/2013	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-001670-27

Protocol serial number
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

Study type(s)
Treatment

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(s)
The aim of the study is to investigate the potential reversibility of the observed impairment of endothelial function.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

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

Sponsor information

Organisation
University of Glasgow (UK)

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow (UK)

Alternative Name(s)
The University of Glasgow

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	01/01/2009		Yes	No