

Reversibility of cerebrovascular endothelial dysfunction in patients with diabetes

Submission date
08/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
27/10/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
23/08/2013

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

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)

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