

Reversal of cerebrovascular endothelial dysfunction in diabetes: the effect of allopurinol upon cerebrovascular nitric oxide bioavailability

Submission date
09/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/11/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
05/01/2009

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Treatment with a xanthine oxidase inhibitor will improve cerebrovascular reactivity in patients with diabetes.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes

Interventions

Two weeks allopurinol versus lactose capsule.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Allopurinol

Primary outcome measure

The change in internal carotid artery flow following L-NMMA infusion.

Secondary outcome measures

1. Change in serum urate level
2. Change in middle cerebral artery flow velocity

Overall study start date

01/11/2005

Completion date

01/11/2006

Eligibility**Key inclusion criteria**

1. Type II diabetes less than 5 years duration, treated with diet, metformin thiazolidinediones or a combination
2. Aged greater than 40 years
3. Normal full Bruce protocol exercise treadmill testing (ETT)
4. Favourable temporal bony window
5. HbA1c less than 9%
6. Cholesterol less than 7.5 mmol/l

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

24

Key exclusion criteria

1. Greater than 70% Internal carotid artery stenosis
2. Known coronary artery disease
3. Other significant comorbidity
4. Contraindication to allopurinol
5. Concurrent therapy with azathioprine or 6-mercaptopurine
6. Insulin or sulphonylurea treatment
7. Serum creatinine greater than 250 μ mol/l

Date of first enrolment

01/11/2005

Date of final enrolment

01/11/2006

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Department of Medicine & Therapeutics

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

Greater Glasgow NHS Board/Glasgow University (UK)

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Government

Funder Name

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