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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

Registration date
22/11/2005

Overall study status
Completed

Last Edited
05/01/2009

Condition category
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

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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 µmol/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)

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Sponsor type
Not defined

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name

Chief Scientist Office of the Scottish Executive Health Department (UK)

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