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Glutathione status in platelets from patients with Type 2 Diabetes: therapeutic potential of N-Acetylcysteine (NAC) to help prevent platelet hyperaggregability

Submission date
03/02/2011

Recruitment status
No longer recruiting

Registration date
03/05/2011

Overall study status
Completed

Last Edited
03/09/2012

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
CZB/4/622

Study information

Scientific Title
Glutathione status in platelets from patients with Type 2 Diabetes: therapeutic potential of N-Acetylcysteine (NAC) to help prevent platelet hyperaggregability, a double-blind placebo-controlled randomized crossover study

Acronym
NAC study

Study objectives
Oral NAC has efficacy in preventing hyperactivity of platelets in type 2 diabetes, either as an adjunct to existing therapy or as an independent anti-thrombotic agent available to patients contraindicated for aspirin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, ref no: 06/S0901/39, Approval granted : 27th Nov 2006. AM01 Dec 2006, AM02 Nov 07, AM03 17/03/09, AM04 (minor) 08/06/09

Study design
Double-blind placebo-controlled randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 Diabetes

Interventions

1. This is a double-blind, placebo-controlled randomised crossover study to investigate the impact of oral dosing (1200 mg/day) with the anti-oxidant N-acetylcysteine (NAC) for 1 week on platelet activity and fibrinolytic potential in patients with type 2 diabetes who are either not receiving (Group A) or are receiving (Group B) aspirin
2. After 1 week on either placebo or NAC, patients will 'cross over' to the alternative treatment arm following a 1 week wash out period. Thus, trial medication will be taken for 2 weeks per patient (1 week on NAC, the other on placebo) over a total period of 3 weeks. The total timeframe of the study is envisaged to be less than 1 year from the start date.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Determine the clinical potential of NAC as an anti-thrombotic agent in patients with type-2 diabetes, either alone or as an adjunct to aspirin therapy
1.1. Degree of platelet activation using flow cytometry and platelet aggregometry ex vivo
1.2. Plasma tissue plasminogen activator (t-PA) expression and activity
1.3. Plasminogen activator inhibitor (PAI-1) expression and activity measured at baseline, Day 7, 15 and 21

Secondary outcome measures
1. To determine whether oral dosing with NAC has the same impact on platelet biochemistry and activity, as found with the study in vitro, described above
2. To establish whether fibrinolysis is also affected by oral dosing with NAC in patients with type 2 diabetes

Overall study start date
12/01/2010

Completion date
25/08/2010

Eligibility

Key inclusion criteria
1. Adult type-2 diabetes patients (men or post-menopausal women)
2. Either not receiving (group A) or receiving (group B) aspirin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
22 (in each group)

Key exclusion criteria
1. Glycated haemoglobin (HbA1c) greater than 10%
2. Random triglyceride greater than 4 mmol L-1
3. Creatinine > 150 Ýmol L-1
4. Current or recently stopped (less than 6 months) smoking
5. Receiving other antiplatelet therapy or lipid lowering therapy
6. Asthma sufferer
7. Current use of tetracycline or cough suppressants

Date of first enrolment
12/01/2010

Date of final enrolment
25/08/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Diabetes and Cardiovascular Science
Inverness
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Sponsor information

Organisation
NHS Highland Health Board (United Kingdom)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (CSO) - Scottish Health Executive (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?
Results article	results	01/11/2012		Yes	No