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Early Metabolic Changes with Thiazide or Beta Blocker Therapy for Essential Hypertension

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 17/04/2012	**Condition category** Circulatory System	

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
N0544160627

Study information

Scientific Title

Study objectives
Can the oral glucose tolerance test detect changes after 4 weeks treatment with thiazide diuretics or beta blockers or combination of the two?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 5 August 2008: approved by Cambridge Research Ethics Committee on 26/11/04.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Hypertension

Interventions
Drug(s) vs placebo.
Blood samples for glucose and insulin determination. Collected by Research team/CIW staff.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Atenolol, bendrofluazide

Primary outcome measure
Change in 2 hour glucose between any drug/drug combination versus placebo.

Secondary outcome measures
Added 5 August 2008:
1. Do patients show a similar change in glucose tolerance after thiazide or beta blocker treatment?
2. Does the combination of drugs cause a greater reduction in glucose tolerance than expected from the response to each drug alone?

Overall study start date
01/02/2005

Completion date
01/02/2008

Eligibility

Key inclusion criteria
Non-diabetic patients who are diagnosed as having essential hypertension will be recruited.

We will be comparing the two most commonly used drugs to treat hypertension, atenolol and bendrofluazide, in patients for whom the drugs (and the doses to be used) are licenced.

We propose an initial open label pilot study of 10-12 patients to confirm final doses to be tested, the duration of therapy for optimum timing of the OGTT and tolerability of doses selected. The pilot study will also be used to confirm sample size calculations for the main study. The protocol for the pilot study will be identical to the main study, but there will not be a placebo phase and the treatment will not be blinded.

The main study will be double-blind, placebo controlled, cross-over study, of approximately 66 patients in which each patient receives in random order, 4 weeks treatment with either Bendrofluazide 5-10mg daily, Atenolol 50-100mg daily or combination of Bendrofluazide 2.5-5mg and Atenolol 25-50mg daily. There will be a forced titration from the lower to the higher dose stated half way through each dosing period. There will be a 1 month placebo wash-out between each dosing period.

At 0, 2 and 4 weeks of each treatment phase, patients will attend the Clinical Investigation Ward (CIW), fasting, for performance of an oral glucose tolerance test (OGTT). Blood will be drawn from an intravenous cannula, for the measurements of glucose and insulin at 0, 1 and 2 hours.

Blood pressure will be measured at each study visit using an Omron machine. The patients will also be given a blood pressure machine to take home and will be asked to measure and record their blood pressure at least twice per week. If their blood pressure is under 110/70mmhg or over 160/110mmHg at any time or if the patient has symptoms e.g. headache or dizziness, the patient will be asked to contact study staff. If the blood pressure remains over 160/110 for two measurements, then another antihypertensive therapy may be commenced, or the patient withdrawn from the study. If blood pressure is < 110/70 mmHg with symptoms then a decision may be made to terminate their participation in the study.

The doses of drugs to be used, while commonly used for angina and oedema, are higher than now commonly used for hypertension. We expect them to be well tolerated during short term use. These doses have also been chosen because they will enable genetic studies top be performed subsequently in a large number of patients.

Prof M Brown and Clinical Pharmacology Unit team has experience of many research studies in the treatment of hypertension. The design of this study has been derived partly from previous experience from these studies and from patient suggestions from these studies.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Pilot: 12, main study: 66

Key exclusion criteria
1. Any patient already taking thiazide diuretics or beta blockers in whom these drugs cannot be switched to alternative drugs with similar or better blood pressure control.
2. Any patient who is intolerant of these medications will be excluded from the study.

Date of first enrolment
01/02/2005

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box No 110
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Sponsor information

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK) - NHS Research and Development Support Funding

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	01/05/2012		Yes	No