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A study to examine the impact of blockade of the renin-angiotensin system on vascular compliance measurements in subjects with type 2 diabetes mellitus complicated by nephropathy

Submission date
12/09/2003

Recruitment status
Stopped

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
22/09/2009

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Protocol serial number
N0237109527

Study information

Scientific Title

Study objectives
The aims of this study are to examine the two null hypotheses stated below and, as a secondary measure, to evaluate the relationship between urinary protein excretion and vascular compliance.
1. There is no difference in the effect of ramipril or irbesartan on vascular compliance measurements in subjects with type 2 diabetes complicated with nephropathy
2. Combination therapy with ramipril and irbesartan does not confer any additional effect on vascular compliance when compared to each drug used in isolation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind controlled crossover group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vascular compliance

Interventions
Please not that as of 22/09/09 the status of this trial has been changed to "Stopped". The trial did not commence due to funding and resource issues

Double blind randomised cross over design clinical trial. Subjects will be randomised to receive an angiotensin converting enzyme (ACE) inhibitor, ramipril plus placebo, or AT2 receptor antagonist, irbesartan plus placebo, or ramipril plus irbesartan for 6 weeks in maximum doses.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ramipiril, irbesartan

Primary outcome(s)
1. Vascular compliance
2. Blood pressure
3. 24 h protein excretion
4. Adverse events

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/02/2004

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
42 Patients over 18 years of age.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2002

Date of final enrolment
01/02/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Research Registrar
Prescot, Merseyside
United Kingdom
L35 5DR

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Helens and Knowsley Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration