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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 | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 12/09/2003 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 12/09/2003 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 22/09/2009 | Nutritional, Metabolic, Endocrine | [ ] 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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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
1. Vascular compliance
2. Blood pressure
3. 24 h protein excretion
4. Adverse events

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/02/2002

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
42

### 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**
England

United Kingdom

**Study participating centre**
**Research Registrar**
Prescot, Merseyside
United Kingdom
L35 5DR

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
St Helens and Knowsley Hospitals NHS Trust (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