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Consequences of chronic kidney disease (CKD) in older people

Submission date	Recruitment status	[_] Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/12/2019	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6258

Study information

Scientific Title
Cardiovascular and functional consequences of chronic kidney disease in older people: a single centre non-randomised interventional treatment trial

Study objectives

The aim of this study is to investigate this area with an integrated range of non-invasive assessments, both without antihypertensive medication, and with BP control to published best-practice guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent MREC, 15/03/2007, ref: 06/MRE04/73

Study design
Single centre non-randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions
Antihypertensive therapy using standard agents to target BP 130/80 mmHg. Assessments are performed after antihypertensive washout, reintroduction and 12 months follow up.

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Changes in Baroreflex sensitivity (a composite marker of autonomic function) in response to antihypertensive therapy, assessed at each assessment

Key secondary outcome(s))
Assessed at each assessment:
1. Cardiovascular predictors of Falls propensity
2. Cardiovascular consequences of antihypertensive therapy

Completion date
08/02/2010

Eligibility

Key inclusion criteria
1. Aged greater than 70 years
2. CKD 3, 4 or hypertensive (greater than 130/80) with no renal disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Use of more than 3 drugs for blood pressure control
2. Likely to develop CKD 5 within one year
3. Poor mobility precluding completion of assessment
4. Diabetes
5. Abbreviated mental test (AMT) score < 8
6. Recent acute illness (within 3 months)
7. Ischaemic heart disease requiring beta-blockade (nitrates/nicorandil are permitted)
8. Involvement in another clinical trial within 3 months
9. Attending day hospital or attending falls reduction services
10. Residents in nursing or residential homes
11. Renovascular disease precluding ACE-inhibitor (ACEi) or Angiotensin Receptor Blocker (ARB) usage
12. BP prior to antihypertensive withdrawal > 160/90mmHg
13. Malignant hypertension
14. Severe peripheral vascular disease or significant valvular heart disease
15. Heart failure (NYHA III/IV) or other cause to prevent diuretic withdrawal
16. Atrial fibrillation or other significant arrhythmia (precludes pulse wave velocity (PWV) measurement)
17. Currently taking antihypertensive medication for which MRHA approval (CTA) has not been granted
18. Active Obstructive uropathy

Date of first enrolment
01/08/2007

Date of final enrolment
08/02/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Derby Hospital NHS Foundation Trust (UK)

Funder(s)

Funder type
Research organisation

Funder Name
British Renal Society (UK)

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration