Consequences of chronic kidney disease (CKD) in older people

Submission date	Recruitment status No longer recruiting	Prospectively registered	
19/05/2010		<pre>Protocol</pre>	
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

Contact name

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Contact details

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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

Αll

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

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

Study outputs

Output type Details

Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet

11/11/2025 11/11/2025 No