

Consequences of chronic kidney disease (CKD) in older people

Submission date 19/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/12/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

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

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 measure

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

Secondary outcome measures

Assessed at each assessment:

1. Cardiovascular predictors of Falls propensity
2. Cardiovascular consequences of antihypertensive therapy

Overall study start date

01/08/2007

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

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 80

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

England

United Kingdom

Study participating centre

Royal Derby Hospital

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

Derby Hospital NHS Foundation Trust (UK)

Sponsor details

Royal Derby Hospital

Uttoxeter Road

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DE22 3NE

+44 1332 340131

t.grieve@derbyhospitals.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.derbyhospitals.nhs.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

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