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Comparing intervention to lower systolic blood pressure in chronic kidney disease (CKD): a cluster randomised trial (CRT)

Submission date
21/05/2008

Recruitment status
No longer recruiting

Registration date
12/06/2008

Overall study status
Completed

Last Edited
03/07/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
7395/4843 (HF)

Study information

Scientific Title

Acronym
QI CKD

Study objectives
This cluster randomised trial (CRT) will compare two well-established quality improvement interventions with usual practice. The two intervention arms are:
1. Provision of clinical practice guidelines with prompts
2. Audit-based education

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Oxford Research Ethics Committee (Committee C) on the 31st October 2006 (ref: 07/H0606/141).

Study design
A two-year three-armed cluster randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
The three interventions are:
1. Usual practice: a minimum of contacts will be made of these practices other than for data collection (n = 35 practices)
2. Distribution of clinical practice guidelines with prompts: this is an established, low cost method. It will provide a benchmark with which the effectiveness of other quality improvement interventions can be compared. We will develop a consensus between the study team, our expert advisory group and external peer reviewers', and produce appropriate guidance for the management of CKD in primary care. We will use the "Appraisal of Guidelines Research and

Evaluation" (AGREE) instrument do to this. AGREE is a validated guideline development tool. This guidance will be distributed to practices with quarterly updates/reminders (n = 35 practices). In addition practices will have access to a supportive website with information about CKD, frequently asked questions (FAQs) and tools to improve CKD management.
3. Audit-based education: in addition to clinical practice guidelines, practices will receive six-monthly detailed comparative feedback about their quality of CKD management (n = 35 practices)

The total duration of the intervention is two years.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The reduction of systolic blood pressure in hypertensive people with stage 3 to 5 chronic kidney disease according to the agreed target.

The measure of primary and secondary outcome measures will take place at t = 0 (baseline), t = 1 year and t = 2 years.

Secondary outcome measures
Clinical and laboratory markers:
1. Recording and management of key co-morbidities:
1.1. Diabetes and its complications
1.2. Ischaemic heart disease
1.3. Heart failure
1.4. Obstruction/lower urinary tract symptoms
2. Recording and management of other cardiovascular risk factors:
2.1. Smoking status
2.2. Lipid management
2.3. Proteinuria
2.4. Anaemia
2.5. Glycated haemoglobin and microalbuminuria in people with diabetes mellitus
3. Serial measures of serum creatinine concentration and estimated glomerular filtration rate (GFR)
4. Avoiding harm. We wish to collect data to monitor whether blood pressure reduction is associated with an increased number of falls particularly in older people. Most people with CKD are elderly and at potential risk of falls. Notwithstanding the results of recent systematic reviews which failed to show an association between falls and anti-hypertensive medication, this possibility remains a genuine concern to some practitioners, and one that we propose to examine. A falls dataset will be devised and integrated into the renal dataset. We will investigate the relationship with use of angiotensin converting enzymes (ACE) inhibitors and angiotensin II receptor blockers and systolic blood pressure below 120 in CKD.
5. Practitioner confidence to be measured at t = 0, t = 1 year, and at end of project
6. Medicines management:
6.1. Use of drugs/therapy which affect renal function (for example non-steroidal anti-inflammatory drugs)
6.2. Use of angiotensin converting enzyme inhibitors and angiotensin II receptor blockers to

control hypertension
6.3. Recording of medicines possession ratio based on days prescribed therapy as an index of concordance with anti-hypertensive therapy

The measure of primary and secondary outcome measures will take place at t = 0 (baseline), t = 1 year and t = 2 years.

Overall study start date
01/04/2007

Completion date
01/04/2010

Eligibility

Key inclusion criteria
The primary research participants are general practitioners involved in the study who will receive the various quality improvement interventions listed below. The interventions will be implemented at the practice (cluster) rather than the individual level. The study subjects (who may be regarded as secondary participants) will be all individuals with chronic kidney disease within the study practices.

Inclusion criteria:
1. Practices who provide written consent to participate
2. Locality specialist who will support the participation of the practice and the implementation of standard guidelines across the participating practices (appropriate to the arm of the study they are involved in)
3. Primary Care Trust (PCT) commissioners' engagement with the project and willingness to consider learning from its findings
4. Practice has had the same computer system for the last five years and has no plans to change it, or will allow access to check data quality
5. Practice has electronic laboratory links for the last three years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
105 GP practices

Key exclusion criteria
1. Practices in whom the computing system has changed over the last five years
2. Practices lacking an appropriate computer system from which data can be extracted
3. Practices in which referral data (from primary care to secondary care) is not available

Date of first enrolment

01/04/2007

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department in Health Care
Guildford
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK) (ref: 7395/4843 (HF))

Funder Name
Kidney Research (UK) (ref: CDK/2007)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2013		Yes	No
Other publications	cross-sectional analysis	25/02/2013		Yes	No
Results article	results	10/09/2013		Yes	No