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The Impact of Laboratory-based Prompts on the Management of Patients with Chronic Kidney Disease

Submission date
10/02/2006

Recruitment status
No longer recruiting

Registration date
10/07/2006

Overall study status
Completed

Last Edited
14/02/2008

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N/A

Study information

Scientific Title

Study objectives
A laboratory prompt, which identifies a patient with chronic kidney disease (CKD) as being at high risk for cardiovascular disease and progression to kidney failure, improves the management of cardiovascular disease risk factors and kidney disease by physicians.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Bioethics Committess at the University of Calgary and the University of Alberta, 2005, reference number: 18050

Study design
Cluster randomized trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
The following prompt will be added to laboratory reports for patients who meet the inclusion criteria and are seen by a physician practice randomized to receive the prompt:
This patient has reduced kidney function and is at risk for cardiovascular events and progression to kidney failure. The National Kidney Foundation recommends:
1. Measure random urine albumin to creatinine (Alb:Cr) ratio
2. Institute an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) in patients with diabetes, or those with an Alb:Cr >35 mg/mmol
3. Referral to a nephrologist if GFR <30 ml/min/1.73 m^2
4. Assess and treat modifiable risk factors for cardiovascular (CV) and renal disease:
a. Target blood pressure (BP) less than 130/80 mmHg
b. Target low-density lipoprotein cholesterol(LDL-C) <2.5 mmol/l
c. If diabetic, target hemoglobin A1C (HbA1C) <7.0%

The above recommendations are general in nature and may not apply to all patients. Further information is available at http://www.akdn.info
The control group will receive usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Use of ACEi or ARB in patients >65 years of age with CKD who have a clear indication for ACEi or ARB use as defined by the presence of diabetes or significant albuminuria.

Key secondary outcome(s))
1. Use of an ACEi or ARB in patients >65 years of age with CKD
2. Subsequent measurement of lipids, hemoglobin A1C (in patients with diabetes, if not done in previous six months), urine protein or urine albumin, and subsequent frequency of measurement of serum creatinine
3. Referral to a specialist
4. Addition of cholesterol-lowering drugs in patients >65 years of age
5. Addition of new blood pressure medication(s) in patients >65 years of age
6. Health care costs

Completion date
31/03/2008

Eligibility

Key inclusion criteria
All patients >18 years of age who are registered with one of the participating general practices and have a GFR measured at <60 ml/min during the one-year study period will be included. All participating general practices will be geographically separated (not located in the same office building), and staffed by >1 full time practitioners who do not see outpatients in another general practice unit (to reduce the risk of contamination).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Those patients not meeting the inclusion criteria.

Date of first enrolment
01/04/2006

Date of final enrolment
31/03/2008

Locations

Countries of recruitment

Canada

Study participating centre
1403-29th St NW
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Sponsor information

Organisation
Alberta Heritage Foundation for Medical Research (Canada)

ROR
https://ror.org/006b2g567

Funder(s)

Funder type
Research organisation

Funder Name
Alberta Heritage Foundation for Medical Research (Canada)

Alternative Name(s)
AHFMR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration