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A cluster randomised trial to assess the impact of opinion leader endorsed evidence summaries on improving quality of prescribing for patients with chronic cardiovascular disease

Submission date
04/06/2005

Recruitment status
No longer recruiting

Registration date
14/06/2005

Overall study status
Completed

Last Edited
21/09/2007

Condition category
Circulatory System

[_] Prospectively registered
[X] 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

ClinicalTrials.gov (NCT)
NCT00175279

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
We propose having locally-nominated opinion leaders generate and endorse one-page evidence summaries for two common and chronic cardiovascular conditions. These evidence summaries, linked with specific patient-level medication profiles (generated at the community pharmacy), will be distributed to practicing physicians and attached to their patients chart. Our hypothesis is that this will act as both a source of credible and convincing information and a specific reminder for action at the next patient encounter. Our study is designed to test this hypothesis, by assessing the impact of this intervention on the quality of prescribing for patients with Heart Failure (HF) or Ischaemic Heart Disease (IHD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure, ischaemic heart disease

Interventions
The intervention consists of a disease-specific and patient-specific one-page evidence summary. It will be a patient-specific letter addressed to the patients primary care physician, along with a description of the potential risks of undertreatment and current evidence-based treatment recommendations. The letter will be signed and endorsed by all five of the study opinion leaders. Accompanying the letter will be the most recent pharmacy record of medications dispensed to the study patient. It is intended that the evidence summary and the pharmacy medication profile will become part of the patients medical record and act as a reminder or prompt at the next patient visit. These materials will be faxed to the primary care physician directly from the patients community pharmacy.

Control: usual care

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
The primary outcome measure will be the 'improvement' of prescribing for efficacious therapies in patients with a chronic cardiovascular disease within 6 months of the intervention. By study design, none of the study patients will be taking the medications of interest. For HF, starting any ACE inhibitor or angiotensin receptor blocker will be considered a positive outcome. For IHD, starting any statin will be considered a positive outcome. For the primary outcome all positive study-related medication changes will be pooled for an overall estimate of effect, compared with usual care controls.

Key secondary outcome(s))
1. Condition-specific 'improvement' in prescribing after 6 months
2. 'Optimization' of dosage for each of the medications prescribed (i.e. ACE inhibitors or angiotensin receptor blockers and statins)
3. Patient adherence (using prescription refill rates based on dispensing records)
4. Potential influence of age and sex on outcomes

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Patients with HF or IHD who are not currently taking the study medications of interest (Angiotensin-Converting Enzyme [ACE] inhibitors/angiotensin receptor blockers for HF or statins for IHD), and whose primary care physician of record is part of the study. For patients who happen to be eligible for both HF and for IHD, only one condition will be selected at random.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Decline enrolment
2. Unable or unwilling to give informed consent
3. Have previously taken the study medications according to dispensing records
4. Have a documented allergy or intolerance to study medications according to pharmacist records
5. Are in long-term care facilities or institutions
6. Do not confirm on the basis of self-report that they have a diagnosis of either HF or IHD
7. Primary care physician has already contributed 5 patients to the study

Date of first enrolment
01/01/2002

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Canada

Study participating centre
2E3.07 WMC
Edmonton, Alberta
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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

Funder Name
Institute of Health Economics (Canada)

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?
Results article	Results	01/01/2007		Yes	No
Protocol article	Protocol	27/06/2005		Yes	No