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Cost information for prescription drugs through an integrated electronic prescribing system

Submission date	Recruitment status	[X] Prospectively registered
29/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2019	Circulatory System	

Plain English summary of protocol

Background and study aims.
The potential benefits of new drug treatments and increased medication use have not been fully realized, even though the proportion of health costs due to drug costs continues to rise on a yearly basis. This has created a need to investigate new methods to maximize the benefits of existing and new drug treatments while minimizing costs. This research will build on North American initiatives to implement electronic prescribing and integrated drug management systems to improve safety. The study will assess whether access to detailed comparative information on patient out-of-pocket cost for drugs of equivalent effectiveness at the time of prescribing will reduce the overall cost of medication prescribed for elderly patients. The intervention will target medications commonly used to treat cardiovascular disease, high cholesterol, acid-peptic disease, and common chronic respiratory problems. It will also determine the impact on patient adherence with the targeted prescription medications. The results of this research will help to assess the degree to which evidence-based decision-support systems for chronic disease management can be integrated into drug management systems and produce improvements in quality and outcome of care by primary care physicians.

Who can participate?
Physicians are eligible for inclusion if they are primary care practitioners who treat elderly patients and are participating in part or full-time practices in Quebec City, Montreal, or Boston in the electronic prescribing and integrated electronic medical record projects (MOXXI in Quebec and the Partners Healthcare Longitudinal Medical Record with RxHub in Boston).
Patients will be eligible for inclusion in the study if they are 65 years of age or older, and make one or more visits to an enrolled study physician during follow-up. Only patients who have been prescribed or dispensed one or more of the target medications (i.e. antihypertensives, lipid-lowering drugs, anti-ulcer drugs, and drugs for asthma and COPD) during follow-up will be eligible.

What does the study involve?
A study with 12 months of follow-up will be conducted in 100 primary care clinics, representing 300 physicians and 52,852 of their elderly patients. Clinics, sorted by city, size, and baseline drug costs for elderly patients, will be randomly allocated to receive a) comparative expected patient out-of-pocket expenditure information or b) the integrated drug management/electronic record

system alone. Comparative expected patient out-of-pocket expenditure information will be provided for elderly patients receiving drug treatment for cardiovascular disease, hyperlipidemia, acid-peptic disease, and common chronic respiratory problems as drug treatment for these conditions is responsible for 65% of the drug budget and is the fastest growing sector of expenditure.

What are the possible benefits and risks of participating?
This study involves minimal to no risk.

Where is the study run from?
The study is run from Quebec City and Montreal, Quebec, Canada and Boston, MA, USA

When is study starting and how long is it expected to run for?
The study started on January 1st, 2009 and is expected to run until January 1st, 2014

Who is funding the study?
Canadian Institutes of Health Research (CIHR)

Who is the main contact?
Dr. Robyn Tamblyn
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Study website
http://www.moxxi.mcgill.ca

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-82331

Study information

Scientific Title
Providing comparative out-of-pocket cost information for prescription drugs through an integrated physician electronic prescribing system: a proof of concept with anti-hypertensive drugs

Study objectives
The primary objective is to determine if provision of comparative information on expected out-of-pocket expenditures for anti-hypertensive drugs to physicians at the time of prescribing for uncomplicated hypertension therapy will increase the proportion of patients receiving more cost-effective treatment. The secondary objective is to determine if primary and secondary adherence with anti-hypertensive medication is improved by providing physicians with information needed to reduce out-of-pocket expenditures for anti-hypertensive treatment.

As of 14/06/2012, the following changes have been made on the trial record:
1. Anticipated start date has been amended from 01/07/2007 to 26/01/2009.
2. Anticipated end date has been amended from 01/07/2009 to 31/10/2013.

Please note that as of 30/04/2013, the following changes have been made to the trial record:
1. The anticipated start date of this trial has been updated from 26/01/2009 to 01/01/2009
2. The anticipated end date of this trial has been updated from 31/10/2013 to 01/01/2014

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of McGill University/Université McGill approved on the 20th September 2006 (ref: A07-B27-06b)

Study design
Cluster randomised single blind (study participant, caregiver, outcome assessor, data analyst), single centre, interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Uncomplicated hypertension

Interventions
1. Control: basic integrated prescribing and medical record system
2. Experimental: control and comparative information on out-ot-pocket expenditures at time of prescribing

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Monthly cost of prescription(s) for uncomplicated hypertension at last date of prescribed or dispensed anti-hypertensive medication in the 12-month follow up period.

Secondary outcome measures
Primary and secondary adherence to anti-hypertensive medication during last six months of follow up.

Overall study start date
01/01/2009

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Male or female subjects, 18 years of age or older
2. Make one or more visits to an enrolled study physician during follow-up
3. Have a diagnosis of uncomplicated hypertension (i.e. hypertension recorded by the study physician in the therapeutic indication field that must be completed with each prescription)
4. No documented diabetes, congestive heart failure, established atherosclerotic disease, peripheral arterial disease, ischaemic heart disease (angina or prior myocardial infarction), past cerebrovascular accident or transient ischaemic attack (TIA), renal disease, asthma, chronic obstructive pulmonary disease (COPD) or left ventricular hypertrophy

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8733 patients, 97 primary care physicians

Key exclusion criteria
1. Documented diabetes
2. Congestive heart failure
3. Established atherosclerotic disease
4. Peripheral arterial disease
5. Ischaemic heart disease (angina or prior myocardial infarction)

Date of first enrolment
31/05/2011

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Canada

Study participating centre
Université McGill
Montreal, Quebec
Canada
H3A 1A3

Sponsor information

Organisation
McGill University (Université McGill) (Canada)

Sponsor details

845 Sherbrooke Street West
James Administration Bldg., Suite 429
Montreal, Quebec
Canada
H3A 2T5

Sponsor type
University/education

Website
http://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-82331)

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	10/01/2018		Yes	No