ISRCTN63455839 https://doi.org/10.1186/ISRCTN63455839

Effectiveness of a pharmacist-acquired medication history in an emergency department

Submission date
28/06/2012

Recruitment status
No longer recruiting

Registration date
14/08/2012

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Medication errors are one of the main causes of avoidable damage suffered by patients. They significantly increase morbidity (illness), hospital stay and mortality (death rates). The aim of this study is to assess the effectiveness and safety of a pharmacist-acquired medication history, to see whether it reduces and prevents medication discrepancies in patients admitted to emergency services.

Who can participate?
Patients aged 18 and over who are admitted to hospital and have been prescribed at least one prescription medication before admission

What does the study involve?
A team of pharmacists obtains a history of the drugs all of the patients are currently taking before they are seen by a doctor. The patients are then randomly allocated to one of two groups. One group is included in the MedRec programme (intervention group) and the other group receives standard care. For the intervention group the medication history is available to be used by the doctor during the consultation. For the control group the medication history is given to doctors at a later stage for them to amend prescriptions. Another team of pharmacists obtains the medication history of each patient 24 hours after admission. Another independent team, consisting of a pharmacist and a doctor, carries out the MedRec procedure by comparing the two medication histories. The medication history prepared by the pharmacist and the prescriptions issued by the emergency doctor are compared to identify discrepancies which may have arisen during the admission procedure. If there are any differences then these are clarified and resolved.

What are the possible benefits and risks of participating?
The main benefits are reducing and preventing medication discrepancies. This study involves no risk for the patients.

Where is the study run from?
National University of Colombia (Columbia)

When is the study starting and how long is it expected to run for?
August 2012 to October 2012

Who is funding the study?
National University of Colombia (Columbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FIS-01

Study information

Scientific Title
Effectiveness of a Pharmacist-acquired medication History in an Emergency department: a randomized controlled trial

Acronym
EPHE

Study objectives
The Intervention (a pharmacist-acquired medication history in an emergency department) reduces the number of patients with at least one admission medication discrepancies related to home medications.

Ethics approval required

Old ethics approval format

Ethics approval(s)
University Hospital of the Samaritan woman (Hospital Universitario de la Samaritana), Bogotá, ethics approval committee by Act 142, 27/06/2012

Primary study design
Interventional

Study design
Multicenter randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Medication reconciliation

Interventions
One group of patients will be included in a MedRec programme (intervention group) and the other used for comparison/control. A team made up of pharmacists, blinded to the assignation and intervention, will obtain the clinical history regarding the drugs which a particular patient is currently consuming in his/her home (R1). The participants will then be randomly assigned to the intervention or control group by simple randomisation using a random number table and data stored on an Excel calculation spreadsheet. The assignation will be concealed by using sequentially-numbered, sealed opaque envelopes, in sequentially-numbered, sealed containers; there will be two exactly similar copies which will be guarded under lock and key by the emergency coordinator. Another team of pharmacists blinded to the patients assignation and each intervention and control group will prospectively obtain the medication history for each patient being attended by the emergency service (R2).

Another independent team, consisting of a pharmacist and a doctor, will carry out standardized MedRec procedure by comparing R1 to R2. The medication history prepared by the pharmacist in triage and that regarding prescriptions issued by the emergency doctor will also be compared to identify discrepancies which may have arisen during the admission procedure. If there are any differences then these will be clarified and resolved, leading to corrected medical orders and MedRec history (R3) being established for all patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Medication discrepancies associated with the intervention. The following definition of medication discrepancy has been adopted for the present study: Any patient medication-related statement regarding medication consumed at home, made during admission to the emergency service. Discrepancies will be prospectively identified. The main result will lie in identifying patients having at least one discrepancy regarding the medication being taken at home, then recording it and communicating it.

Medication discrepancies may be associated with drugs, medication brand-name, dose, duration, frequency, formulation, administration route, resumption of appropriate medication, illegible medical orders/prescriptions.
Identifying the type of discrepancy: Detecting the presence of some of the following events:
1.1. Omission (not ordering medication which a patient has been taking before admission)
1.2. Therapeutic duplicity (receiving more than one similar medication for the same indication)
1.3. Slowness in resuming therapy (selecting one of the following categories: before 6 hours, 6-12 hours, 12-24 hours or more than 24 hours after being admitted)
1.4. Therapy instituted too soon (i.e. treatment being reinitiated without taking frequency of taking a prescribed drug at home into account: before 6 hours, 6-12 hours, 12-24 hours or more than 24 hours)
2. Prescription discrepancies
2.1. Inconsistency or omission of some type of the following information: medication brand-name, dose, frequency, administration route or illegible orders
2.2. Prescription omission (when a patient has been given medication which has not been prescribed)
2.3. Medications lacking indication (medication administered without any indication, not associated with a diagnosis or consuming unneeded medication)
2.4. Allergies and interactions (these should be classified according to the following categories: higher (interaction could affect a patients life or cause permanent damage must be suspended immediately), moderate (when this does not put a patients life at imminent risk but could complicate his/her general state and lead to reversible damage), lower (not affecting a patients clinical condition but could involve adjusting the dose), none (interaction is present but documentation is lacking regarding the clinical effect), others (some of those which are not described in this protocol but which could be of clinical interest).
Number of discrepancies per category. Describing events which could arise: omission, therapeutic duplicity, slowness in resuming therapy, therapy instituted too soon, prescription discrepancies, prescription omission, medication lacking indication, allergies, interactions, other events.

Key secondary outcome(s)

Classifying and evaluating discrepancy safety: Involuntary medication discrepancies which may cause damage are defined as, An incident potentially leading to a medication-related lesion. The potential to cause damage has been used to measure medication safety and its reduction as an action to reduce real medical administration records (RAM). Discrepancy risk has been defined in three classes (according to Cornish et al.):
1. Class 1 (those probably not causing clinical deterioration or nuisance)
2. Class 2 (those having the potential to cause moderate nuisance or clinical deterioration)
3. Class 3 (those having the potential to cause serious discomfort for a patient or significant clinical deterioration)

Characterising the population seeking help from emergency services will involve recording date regarding chronological age in years, gender, socioeconomic strata, number of prior hospitalisations, number of morbidities, type of co-morbidity, how many medications are being taken, the type of medication and interventions made by the pharmacist.

Characterizing and evaluating reconciliation will involve evaluating the opportunity and suitability of pharmaceutical action. The number of interventions made by a pharmacist will be measured, as will the medication historys level of acceptance and average time spent on MedRec in hours.

Completion date

15/10/2012

Eligibility

Key inclusion criteria
1. Adults (aged 18 or over)
2. Patients admitted and assessed as triage I and II
3. Prescribed at least one prescription medication before admission
4. To be hospitalized for at least 24 hours
5. Only patients with a time admission income less than 24 hours and
6. Had signed study participation agreement and completion of informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. They are scheduled for discharge on the same day
2. They are not able to answer the questions needed to complete the study
3. They are unable to communicate due to language difficulties, were under psychiatric care, medical record documentation of dementia or confusion and/or are unable to give consent. If a patient had more than one admission during the study period, only the first admission will be evaluated

Date of first enrolment
15/08/2012

Date of final enrolment
15/10/2012

Locations

Countries of recruitment
Colombia

Study participating centre

Universidad Nacional de Colombia
Bogota
Colombia
14490

Sponsor information

Organisation
National University of Colombia (Universidad Nacional de Colombia) (Colombia)

ROR
https://ror.org/059yx9a68

Funder(s)

Funder type
University/education

Funder Name
Research Division Bogota (DIB) - National University of Colombia [División de Investigación Bogotá (DIB) Universidad Nacional de Colombia, Código QUIPU] (Colombia)

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	29/08/2013		Yes	No
Results article	results	20/08/2015		Yes	No