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The effect of emergency department pharmacists on drug overuse and drug underuse in patients with an adverse drug event (ADE)-related hospitalisation

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
06/03/2022

Overall study status
Completed

Last Edited
27/08/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Background and study aims
Drug overuse or drug underuse are the most common causes of adverse drug events and can lead to hospital admissions. Using clinical pharmacists in the emergency department (ED) may improve patient safety as they are specialised in recognising adverse drug events (ADE) and tackling drug overuse and drug underuse. This study tested the effect of an emergency department pharmacist on the number of medication changes for drug overuse and drug underuse taking place in patients with an adverse drug event-related hospitalisation following an emergency department visit.

Who can participate?
Patients of 18 years and older visiting the ED and are hospitalised.

What does the study involve?
Intervention of ED pharmacist to detect potential ADEs as reason for admission, perform pharmacist-led medication review in those patients, feedback session with patients and transmission of medication changes to the next healthcare giver after hospital discharge.

What are the possible benefits and risks of participating?
Benefit: Pharmacist led medication review to reduce drug overuse and drug underuse to prevent the continuation of drug-related problems which can lead to hospitalisation.
No risks.

Where is the study run from?
The study is carried out in the Erasmus Medical center and the OLCG hospital, both based in The Netherlands.

When is the study starting and how long is it expected to run for?
June 2016 to January 2018

Who is funding the study?
Innovation Fund of Dutch Healthcare Insurance Companies (the Netherlands)

Who is the main contact?
Rehana Rahman, r.n.rahman@umcg.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

MEC-2016-346

Study information

Scientific Title
The effect of a pharmacist-led medication review on reduction of drug overuse and drug underuse in patients with an ADE-related hospital admission after ED visit compared to regular care

Acronym
SHARM

Study objectives
Intervention of ED pharmacists can led to detection of adverse drug event-related admissions and reduce drug related problems such as drug overuse and drug underuse

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee (METC) Erasmus MC Rotterdam approved the study and decided that it was outside the scope of the Human Research Act. The approval of METC Erasmus MC Rotterdam is registered with number MEC-2016-346 on 14-06-2016.

Study design
Prospective multicenter non-randomized controlled intervention study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files (in Dutch)

Health condition(s) or problem(s) studied
Patients visiting the emergency department with an adverse drug event

Interventions
Intervention group: regular care + the interdisciplinary intervention consists of a pharmacist-led medication review, patient counselling regarding medication, and information transmission to

general practitioners and community pharmacies after discharge
Control group: regular care during hospitalization
Patients are followed up for six months.

Intervention Type
Behavioural

Primary outcome measure
The number of medication changes for drug overuse and drug underuse that took place during hospital admission and persisted six months thereafter measured using medication overviews and estimate the difference between groups with poisson regression analysis.

Secondary outcome measures
1. The number of all medication changes that took place during admission and persisted six months after discharge measured using medication overviews and estimate the difference between groups with poisson regression analysis.
2. The number of medication changes for drug overuse and drug underuse that took place during admission and all medication changes during admission measured using medication discharge records and estimate the difference between both groups with poisson regression analysis.
3. The proportion of ADEs causing hospitalisations recognised by physicians in the ED measured using discharge letters from the ED of intervention patients at moment of ED visit.
4. The degree of patient satisfaction with the intervention of the ED pharmacist measured in the intervention group using a Visual Analogue Scale (VAS) at three months after admission.
5. The number of (ADE-related) hospitalisations within a period of six months before and after the index admission within the intervention group measured using medical records from general practitioners and the difference between periods will be estimated by a Wilcoxon signed rank test.

Overall study start date
14/06/2016

Completion date
01/01/2018

Eligibility

Key inclusion criteria
Patients aged 18 years and older were eligible for inclusion if they were hospitalised for more than 24 hours after visiting the ED.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
200

Total final enrolment
216

Key exclusion criteria
1. No communication possible due to condition or language barrier
2. Cognitive impairment; transfers to other hospital
3. No pre-admission medication; admission due to problems with cancer treatment
4. Alcohol intoxication and/or (self)poisoning related hospitalisation
5. Psychiatric hospitalisation
6. Intensive care unit (ICU) hospitalisation
7. Foreign tourist or homeless patient
8. Already included patient readmitted within the research period
9. Patients with no informed consent

Date of first enrolment
01/10/2016

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus University Medical Center
Doctor Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
OLVG hospital
Jan Tooropstraat 164
Amsterdam
Netherlands
1061 AE

Sponsor information

Organisation
Erasmus MC

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Innovation Fund of Dutch Healthcare Insurance Companies

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed medical journal.

Intention to publish date
25/02/2021

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study are not publicly available because they contain information that could compromise the privacy of research participants, but are available from the corresponding author upon reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Dutch		04/03/2022	No	Yes
Participant information sheet	in Dutch		04/03/2022	No	Yes
Protocol file	version 1.0	10/05/2016	04/03/2022	No	No
Results article		17/11/2022	22/05/2023	Yes	No
Results article	cost study	23/08/2024	27/08/2024	Yes	No