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Clinical and financial impact of pharmacist interventions during patient rounds in intensive care units

Submission date
03/09/2016

Recruitment status
No longer recruiting

Registration date
21/10/2016

Overall study status
Completed

Last Edited
14/09/2017

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The programme (or intervention) being tested in this study assesses how appropriate medications prescribed to patients being treated in an intensive care unit (ICU) are, how long the treatment with continue, the dosage of medication being given and what effects the medication may have. This study is looking at whether the intervention works well in two different ICUs.

Who can participate?
Patients included in the study are over 18 and being treated at one of the ICUs taking part in the study (Haga Teaching hospital and ErasmusMC University Medical Center)

What does the study involve?
Over a period of three to six months, pharmacists join in patient rounds in one of the two ICU wards participating in the study twice a week. Information gathered on each patient include their medication order, information stored in a electronic data management system and hospital files. As assessment of the medications being prescribed to each patient is then made and the pharmacist makes a recommendation as appropriate. The proportion of pharmacist recommendations that are accepted and acted upon are calculated. Other information collected include how inappropriate the pharmacist considers the medication prescribed to be and costs.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Haga Teaching Hospital and ErasmusMC University Medical Center

When is the study starting and how long is it expected to run for?
July 2008 to September 2016

Who is funding the study?
Haga Teaching Hospital and ErasmusMC University Medical Center.

Who is the main contact?
Mrs Liesbeth Bosma

Contact information

Type(s)
Scientific

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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Study information

Scientific Title
Clinical and financial impact of pharmacist interventions during patient rounds in intensive care units: an intervention study, comparing a university hospital with a general teaching hospital in the Netherlands

Study objectives
Implementation of a clinical pharmacy program in two different ICU settings will result in similar acceptance of the interventions and will be cost effective in both ICU settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was considered a quality improvement study and therefore did not need approval of the Medical Ethics Committee according to Dutch clinical trial law

Study design
Interventional open prospective study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Intensive care

Interventions
A proactive ICU pharmacist intervention method was developed. This intervention method consisted of two elements, namely preparation of the patient rounds by collecting and assessing patient's information and analyzing clinical effects of patient's therapy, and participation in patient rounds.

Preparation of the patient rounds consisted of collecting medication orders and patient information from the electronic patient data management system (PDMS) and the hospital files available, followed by an assessment of appropriateness, indication, duration of therapy, drug dosage and frequency, adjustment to renal function, drug-drug interactions, contra-indications, drug omissions and duplicate medication. Furthermore the clinical effects of the patient's therapy were analyzed. A check on missing (prophylactic) medicines was also performed.

During the patient round the collected interventions were discussed with the attending intensivist.
During the 6-month study period in the General Teaching Hospital, one dedicated pharmacist participated in patient rounds twice a week. During the 3-month study period in the University Hospital four pharmacists participated in the clinical rounds twice a week: Each included patient in the University Hospital was reviewed once a week and in the General Teaching Hospital twice a week.

There was no follow up on the patients after the end of the study period.

Intervention Type
Other

Primary outcome measure
The proportion of pharmacist recommendation interventions on prescribing that were accepted and implemented by the prescriber.

Calculated via the number of recommendation interventions that lead to an actual change in prescribing (nominator) divided by the total number of the recommendation interventions made by the pharmacist (denominator). i.e. if the pharmacist intervened on the prescription by recommending that the doctor stop the drug, and the doctor followed the recommendation and actually stopped the prescription, than the intervention was scored as being accepted by the doctor. This outcome was real time/immediately measured. After the patient round, the prescribing system was checked on actual changes in prescribing. After data collection a cross check was done to verify all collected data.

Secondary outcome measures
1. Intervention severity, assessed according to inappropriateness of the prescription order or its deviation from the standard of practice (according to scale: A =Potentially lethal, B=Serious, C=Significant ,D=Minor, E=No error)
2. Value of service, assessed as the potential impact of the pharmacist's recommendation on patient care (according to scale 1= Extremely significant, 2= Very significant, 3= Significant, 4= Somewhat significant, 5= No significance, 6= Adverse significance)
3. Probability of prevention of an adverse event occurring, assessed using the following score: 0.6 = high (harm is expected, life threatening), 0.4 = medium (harm is expected, clinically relevant), 0.1 = low (some harm is expected, but poorly clinically relevant) , 0.01 = very low (problem orders, clarifications, missing information etc), 0 = zero
4. Cost effectiveness, measured via a preliminary cost benefit analysis using the following variables: costs of service (labour costs), cost savings (through recommendation interventions that directly reduced drug costs) and cost avoidance, (based on ADE probability estimates and ADE unit cost)

All secondary outcomes were created/scored retrospectively (in 2015 -2016). 1, 2 and 3 were scored separately by an intensive care doctor (specialized in internal medicine) and a ICU trained hospital pharmacist, consensus was reached in a consensus meeting. Cost effectiveness was retrospectively measured in 2016.

Overall study start date
01/07/2008

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Patients aged at least 18
2. Staying in the ICU during the patient round in which the pharmacist participates

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
General teaching hospital (GTH): 160 patients, University Hospital (UH): 174 patients

Key exclusion criteria
Participants not fulfilling inclusion criteria

Date of first enrolment
01/07/2008

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Haga Teaching Hospital
The Hague
2504AC

Study participating centre
ErasmusMC University Medical Center
3015CE

Sponsor information

Organisation
Erasmus Medical Centre

Sponsor details
Clinical Pharmacy Department
's-Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Haga Teaching Hospital

Funder Name
Erasmus Medisch Centrum

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Submission of the article in September 2016 in an acute care journal. Publication of all results (clinical and financial) in 1 article.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date