Intensive pharmacovigilance of high-risk patients on hospital surgical wards.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24911

Source
NTR

Brief title
P-REVIEW

Health condition

High risk patients on (orthopaedic) surgical wards

Sponsors and support

Primary sponsor: Canisius Wilhelmina Hospital/
Department Clinical Pharmacy
Radboud University Nijmegen Medical Center
Mevr. J.M. Bos, hospital pharmacist
Dr. C. Kramers, internist-clinical pharmacologist
Source(s) of monetary or material Support: ZonMw (www.zonmw.nl)
KNMP (www,knmp.nl)
UVIT (www.uvit.nl)

Intervention

Outcome measures

Primary outcome

Unintended drug related problems due to prescription errors, that lead to death, disability, increased length of hospital stay and readmission.

Outcomes are judged by opinions of a panel of experts.

Secondary outcome

1. Serious prescription errors;

2. Non-serious prescription errors;

3. Guideline adherence.

Outcomes are judged by opionions of a panel of experts.

A pharmaco-economic evaluation will be performed.

Study description

Background summary

An open intervention, assessment blinded, before/after study in two community hospitals to reduce events (death, disability, increased hospital stay or readmission) due to prescription errors on surgical wards. In this study intensive pharmacovigilance in high risk patients, much less intensive pharmacovigilance in low risk patients and an education program for prescribers. The primary end point of this study is death, disability, increased hospital stay or readmission due to presciption errors. Secundary endpoints are rate of prescription errors, guideline adherence and a pharmaco economic evaluation. Two groups of minimal 5300 patients will be analysed to detect a 50% reduction of events.

Study objective

Intensive pharmacovigilance in high-risk patients, much less intensive pharmacovigilance in low-risk patients and an education program for prescribers will lead to a reduction of medication related events (death, disability, increased hospital stay or readmission) due to prescription errors on (orthopaedic) surgical wards.

Study design

Time schedule of the study:

1. 4 months of preparation of the study;

2. 6 months of usual care period;

3. 3 months of implementation of the intervention;

4. 6 months of intervention period;

5. 5 months of analyzing data and writing of the manuscript.

Intervention

1. A team of hospital pharmacists-clinical pharmacologists and internists-clinical pharmacologist will train participating hospital pharmacists to perform intensive pharmacovigilance in high-risk patients;

2. Selection of high risk patients by a screening method;

3. Intensive pharmacovigilance in high risk patients: Structured medication review will be performed combining clinical data and the list of current medication of the patient;

4. Less intensive pharmacovigilance of low risk patients: Automatically finishing of alerts, which are known to be without harm for low risk patients (90%), without intervention of the hospital pharmacist;

5. Education program for physicians and physician assistants: The most important pharmacologic items will be discussed and national and hospital guidelines, related to these subjects will be explained.

Contacts

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Eligibility criteria

Inclusion criteria

All patients admitted to wards of surgery and orthopaedic surgery of two hospitals during the study period, consisting of 6 months usual care and 6 months intervention (sample size per group is 5300).

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	10600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2676
NTR-old	NTR2804
Other	ZonMw : 171101004
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A