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

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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…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24911

Bron
NTR

Verkorte titel
P-REVIEW

Aandoening

High risk patients on (orthopaedic) surgical wards

Ondersteuning

Primaire sponsor: Canisius Wilhelmina Hospital/
Department Clinical Pharmacy
Radboud University Nijmegen Medical Center
Mevr. J.M. Bos, hospital pharmacist
Dr. C. Kramers, internist-clinical pharmacologist
Overige ondersteuning: ZonMw (www.zonmw.nl)
KNMP (www,knmp.nl)
UVIT (www.uvit.nl)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Canisius Wilhelmina Hospital
Department Clinical Pharmacy
PO box 9015
J.M. Bos
Nijmegen 6500 GS
The Netherlands
+31 (0)24 3657600

Wetenschappelijk

Canisius Wilhelmina Hospital
Department Clinical Pharmacy
PO box 9015
J.M. Bos
Nijmegen 6500 GS
The Netherlands
+31 (0)24 3657600

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	10600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A