

The economic and clinical impact of a clinical pharmacy team on surgical patients: the SUREPILL study.

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The active participation of a clinical pharmacy team on the surgical ward will reduce preventable ADE's cost-effectively.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25425

Bron

Nationaal Trial Register

Verkorte titel

SUREPILL

Aandoening

Adverse Drug Events

Ondersteuning

Primaire sponsor: - Academic Medical Centre Amsterdam

Participating hospitals:

- Onze lieve Vrouwe Gasthuis Amsterdam
- Diakonessenhuis Utrecht

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of preventable ADE's per 100 admissions.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Injuries caused by medication errors are widely agreed to be a problem in hospitalized patients. These injuries are known as preventable Adverse Drug Events (pADE's). Also in The Netherlands is stated that hundreds of people die each year as a result of pADE's. Surgical patients are especially at risk for these ADEs because of the frequent transfer moments within the hospital and subsequent changes in medication.

International studies have shown that hospital pharmacists can effectively reduce pADE's when they actively participate on the ward. This concept is known as 'ward-based pharmacy'. The activities consist of close review of medication on admission, active participation in rounding teams and counselling patients at discharge. The applicability of these findings to the Dutch setting is unknown as our health care system is differently organized. In The Netherlands hospital pharmacists work from a central pharmacy and they are scarce and more costly.

Objective:

The aim of the proposed study is to establish whether the active participation of a clinical pharmacy team on the surgical ward reduces pADE's cost-effectively in the Dutch setting.

Design:

Three hospitals will participate. First, baseline assessments (n=480) will be made in each hospital at the surgical wards. Then, in each centre, one unit will randomly be assigned (one-time randomisation) as experimental unit (n= 482) receiving ward-based pharmacy, whereas the other unit will serve as control unit (n= 482) receiving usual pharmaceutical care.

Population:

Consecutive patients admitted to a surgical ward for elective surgery with an expected length of stay of more than 2 days.

Intervention:

The ward-based pharmacy team assesses medication reconciliation at admission and discharge and daily optimizes the patient medication during hospital stay. Patients admitted to control units receive standard pharmaceutical care.

Outcome measures:

The number of pADE's per 100 admissions in experimental unit patients will be compared to that of control unit patients, corrected for differences at baseline. Besides presence, also the severity of the pADE's will be determined. Additionally, the quality of care will be measured using newly developed quality indicators. The follow-up of 3 months will provide information on the outcomes readmissions, quality of life and additional costs after discharge. All interventions by the clinical pharmacy team will be documented.

Doel van het onderzoek

The active participation of a clinical pharmacy team on the surgical ward will reduce preventable ADE's cost-effectively.

Onderzoeksopzet

1. Medication reconciliation at admission and discharge with questionnaire;
2. Daily registration of interventions by clinical pharmacy team;
3. Follow -up by questionnaire within 3 months after admission;
4. Retrospective patient chart analysis to detect ADE's and determine quality of care.

Onderzoeksproduct en/of interventie

Three hospitals will participate. First, baseline assessments (n=480) will be made in each hospital at the surgical wards. Then, in each centre, one unit will randomly be assigned (one-time randomisation) as experimental unit (n= 482) receiving ward-based pharmacy, whereas the other unit will serve as control unit (n= 482) receiving usual pharmaceutical care.

Active participation of a hospital pharmacy team on the surgical ward:

1. Medication reconciliation at admission by pharmacy technicians;
2. Daily review of prescribed medication by hospital pharmacists;
3. Medication reconciliation and counselling at discharge by pharmacy technicians.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Study ward: surgical ward;
2. Elective admitted for surgical procedure;
3. Hospital stay: > 48 hours.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Patient already included in the study;
2. Admitted from other department within hospital or other hospital.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	1444
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	24-03-2010
Soort:	Eerste indiening

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	NL2134
NTR-old	NTR2258
Ander register	ZonMw : 17088.2706
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A