

Preventing hospital admissions by reviewing medication in primary care.

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Medication review in patients at risk for hospital admissions related to medication may prevent these admissions.

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

Samenvatting

ID

NL-OMON28344

Bron

Nationaal Trial Register

Verkorte titel

PHARM

Aandoening

medication related hospital admissions

Ondersteuning

Primaire sponsor: University Medical Center Utrecht and Utrecht Institute for Pharmaceutical Sciences (UIPS)

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hospital admissions related to medication.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Medication can be effective but can also be harmful and even cause hospital admissions. Medication review or pharmacotherapy review has often been proposed as a solution to prevent these admissions and to improve the effectiveness and safety of pharmacotherapy. However, most published randomised controlled trials on pharmacotherapy reviews showed no or little effect on morbidity and mortality. Therefore we designed the PHARM (Preventing Hospital Admissions by Reviewing Medication)-study with the objective to study the effect of the total pharmaceutical care process on medication related hospital admissions and on adverse drug events, survival and quality of life.

Methods/Design:

The PHARM-study is designed as a cluster randomised, controlled, multi-centre study in an integrated primary care setting. Patients with a high risk on a medication related hospital admission are included in the study with randomisation at GP (general practitioner) level. We aim to include 14200 patients, 7100 in each arm, from at least 142 pharmacy practices.

The intervention consists of a patient-centred, structured, pharmaceutical care process. This process consists of several steps, is continuous and occurred over multiple encounters of patients and clinicians. The steps of this pharmaceutical care process are a pharmaceutical anamnesis, a review of the patient's pharmacotherapy, the formulation and execution of a pharmaceutical care plan combined with the monitoring and follow up evaluation of the care plan and pharmacotherapy. The patient's own pharmacist and GP carry out the intervention. The control group receives usual care.

The primary outcome of the study is the frequency of hospital admissions related to medication within the study period of 12 months of each patient. The secondary outcomes are survival, quality of life, adverse drug events and severe adverse drug events. The outcomes will be analysed by using mixed-effects Cox models.

Conclusions:

The PHARM-study is one of the largest controlled trials to study the effectiveness of the total pharmaceutical care process. The study should therefore provide evidence as to whether the entire pharmaceutical care process should be implemented in the primary care setting.

Doel van het onderzoek

Medication review in patients at risk for hospital admissions related to medication may prevent these admissions.

Onderzoeksopzet

12 months after inclusion: Final measurements.

Onderzoeksproduct en/of interventie

The intervention consists of a patient-centred, structured, pharmaceutical care process. This process consists of several steps, is continuous and occurs over multiple encounters of patients and clinicians. The steps of this pharmaceutical care process are a pharmaceutical anamnesis, a review of the patient's pharmacotherapy, the formulation and execution of a pharmaceutical care plan combined with the monitoring and follow up evaluation of the care plan and pharmacotherapy. The patient's own pharmacist and GP carry out the intervention.

The control group receives usual care.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 65 years of age or older;
2. Using at least five medicines;
3. Using at least one medicine from ATC group A or B;
4. Being non-adherent to at least one medicine.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Resident in nursing home;
2. Life expectancy of less than 3 months;
3. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	14200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	07-12-2010
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	NL2529
NTR-old	NTR2647
Ander register	METOPP / CCMO : M253 / NL20582.028.07 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A