Research into prevention of medication induced fall incidents.

Gepubliceerd: 16-12-2008 Laatst bijgewerkt: 18-08-2022

The withdrawal, reduction or substitution of fall-risk increasing drugs will reduce fall risk in the elderly.

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

Samenvatting

ID

NL-OMON26171

Bron
NTR

Verkorte titel
ImproveFALL

Aandoening

Fall-related injury of any type requiring consultation to the Emergency Department

Ondersteuning

Primaire sponsor: Erasmus MC (Dr. T.J.M. van der Cammen)
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Incidence of further falls;
2. Negative health effects;

3. Costs per prevented fall.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective/ research questions:

To evaluate the effects and cost-effectiveness of a systematic drug assessment and drug modification in older fallers presenting at the Emergency Department (ED). Based on the results of this study, a clinical protocol will be developed for assessment and modification of drug use among older fallers at the ED.

Study design:

RCT with one intervention and one control group. Older fallers (65+) presenting at the ED, and on 1 or more fall-risk increasing drugs, are eligible. In total 620 patients will be randomized. The intervention group will receive a systematic drug assessment. Fall-risk increasing drugs will be stopped, reduced or substituted by safer drugs where possible. The control group will receive usual care and a systematic drug assessment without drug modification. During 1 year of follow-up, fall incidence, fall-related injuries, medication use, recurrence of (disease)symptoms, and health care consumption (costs) will be registered. Also, patients will complete health-related quality of life questionnaires (SF-12v2 and EQ-5D).

Outcome measures:

Primary outcome parameters will be the incidence of further falls and the possible negative health outcomes of drug withdrawal.

Secondary outcome measures will be fall-related injuries, generic health-related quality of life (HRQOL), compliance and quality adjusted life years.

Data analysis:

The intention-to-treat principle will be followed. The hazard ratio (HR) for falling will be calculated with Cox-regression analyses using the time between the intervention till the first/second fall as the outcome measure.

Economic evaluation:

Cost-effectiveness analysis, including costs per prevented fall as primary outcome measure, and costs per prevented fall-related injury and costs per QALY as secondary outcome measures.

Doel van het onderzoek

The withdrawal, reduction or substitution of fall-risk increasing drugs will reduce fall risk in the elderly.

Onderzoeksopzet

- t=0: Baseline fall-related (drug) assessment;

- t=3, 6, 9, 12 months: fall / health questionnaire;

- t=12 months: final fall-related assessment.

Onderzoeksproduct en/of interventie

Intervention group:

systematic fall-related drugs assessment combined with drug modification.

Control group:

systematic fall-related drug assessment without subsequent drug modification.

Contactpersonen

Publiek

Erasmus MC, Department of Internal Medicine, Section of Geriatric Medicine
P.O. Box 2040

T.J.M. Cammen, van der
Rotterdam 3000 CA
The Netherlands
+31.10.7035979

Wetenschappelijk

Erasmus MC, Department of Internal Medicine, Section of Geriatric Medicine
P.O. Box 2040

T.J.M. Cammen, van der
Rotterdam 3000 CA
The Netherlands
+31.10.7035979

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Fall according to the specified definition;

2. Using at least 1 fall-risk increasing drug;

3. Community-dwelling;

4. Age 65 years or older;

5. Independently ambulant;

6. MMSE 21 points or higher;

7. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Fall not meeting criteria of specified definition;

2. Not using fall-risk increasing drugs;

3. Not community-dwelling (e.g. living in nursing home);

4. Age <65 years;

5. Not independently ambulant;

6. MMSE <21 points;

7. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-10-2008
Aantal proefpersonen:	620
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-12-2008
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	NL1523
NTR-old	NTR1593
CCMO	NL23970.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A