Research into prevention of medication induced fall incidents.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26171

Source
NTR

Brief title
ImproveFALL

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC (Dr. T.J.M. van der Cammen)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Incidence of further falls;

2. Negative health effects;

3. Costs per prevented fall.

Secondary outcome

1. Fall-related injuries;

2. Generic HRQOL;

3. Compliance;

4. Quality Adjusted Life Years;

5. Genetic polymorphisms;

6. Costs per prevented fall-related injury;

7. Costs per QALY.

Study description

Background summary

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.

Study objective

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

Study design

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

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

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

Intervention

Intervention group:

systematic fall-related drugs assessment combined with drug modification.

Control group:

systematic fall-related drug assessment without subsequent drug modification.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2008
Enrollment:	620
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-12-2008

Application type: First submission

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	NL1523
NTR-old	NTR1593
CCMO	NL23970.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A