OPtimising thERapy to prevent Avoidable hospital admissions in the Multimorbid elderly

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28225

Source
Nationaal Trial Register

Brief title
OPERAM

Health condition

Polypharmacy
Multimorbid elderly
Hospital admissions
Medication review

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: European Union and Swiss government

Intervention

Outcome measures

Primary outcome

Primary Outcome Patient-level The primary outcome is defined as the first confirmed DRA after discharge from the index hospitalisation within a period of 12 months. Hospitalisation is defined as a stay in an inpatient hospitalisation for longer than 24 hours. The following will not meet the criteria for a hospitalisation.

- Visits to emergency room without inpatient hospitalisation (even if overnight)

- Hospitalisation or prolonged hospitalisation for diagnostic or elective (surgical) procedures for pre-existing conditions

- Admissions due to deliberate suicide attempts

Confirmation of a drug-related hospital admission will be assessed by an independent and blinded adjudication committee (per site) composed of physicians and pharmacists. Prolongation of the index hospitalisation and prolongation of any following hospitalisations will not be adjudicated for drug-relatedness. Adjudication is done according to specific guidelines (see attachment). Study-level The primary outcome of the trial will be the comparison of the two trial groups with respect to DRA and expressed by the hazard ratio as the primary effect measure.

Secondary outcome

Secondary Outcomes Secondary objectives are to assess the impact of pharmacotherapy optimisation on economic parameters, health care utilisation, falls, mortality, quality of life, polypharmacy, medication changes, activities of daily living, and patient understandings of their medication. A qualitative assessment of patient preference will also be performed. The following secondary endpoints will be analysed: Up to 12 months after inclusion: - Survival (including causes of death) - Hospitalisation - Clinically significant drug-drug reaction (in case of a hospital admission) - Unnecessary drugs (in case of a hospital admission) - Drug underuse (in case of a hospital admission) - Potentially inappropriate medications (in case of a hospital admission) - Healthcare utilisation as measured by all unplanned hospitalisations, scheduled and unscheduled physician consultations (differentiated by profession), and visits to the emergency room without hospital admission - Falls reported by participants, as defined in the corresponding SOP. - Informal care received - Unit costs for participating countries that will stem from external sources -
The cost-effectiveness of the trial intervention by combining clinical data, quality of life data and healthcare utilisation data collected within the trial, and unit costs for participating countries that will stem from external sources. Extrapolation beyond 12 months may be performed to cover longer term effects of the intervention. 2, 6, and 12 months after inclusion:
- Degree of polypharmacy, defined as the number of daily long-term medications - Quality of life as measured by the 5-level version of the European Quality of Life-5 Dimensions questionnaire (EQ-5D) -
Pain/discomfort (EQ-5D) - Basic Activities of Daily Living (ADL) 2 and 12 months after inclusion: - Drug compliance as measured by Medication Adherence Questionnaire (MAQ) developed by Morisky with the addition of one question based on Gehi et al. (“In the past month, how often did you take your medications as the doctor prescribed?”). 2 months after

inclusion: - Patients’ understanding of their medication using the Beliefs about Medicines Questionnaire (BMQ) - Satisfaction with Information about Medicines Scale (SIMS) During index hospitalisation - Direct costs of the intervention

Study description

Background summary

The objective of this RCT is to evaluate whether the Systematic Tool to Reduce Inappropriate Prescribing (STRIP) including STRIP assistant (STRIPA) implemented by an appropriately qualified team will lead to an improvement in clinical and economic outcomes among patients aged 70 years and more with multimorbidity and polypharmacy.

The primary objective is to assess the effect of pharmacotherapy optimisation on drug-related hospitalisations caused by non-preventable adverse drug reactions of preventable medication error related to over-, miss-, and underuse or over-, miss-, and underprescribing of prescription and non-prescription medications.
Secondary objectives will be to assess the impact of pharmacotherapy optimisation by STRIP on economic parameters, health care utilisation, falls, mortality, quality of life, polypharmacy, medication changes, activities of daily living, and patient understanding of their medication and to assess the patient’s perspective on the STRIP.

Study objective

Reducing avoidable hospital admissions in multimorbid elderly by optimising pharmacotherapy using the STRIP method including a webbased decision support software tool with integrated STOPP/START criteria, carried out by a physician and a pharmacist.

Study design

Inclusion will take place during the index hospitalisation

SHiM within 72 hours after admission
Follow-up telephone calls at 2 (±14 days), 6 (±28 days), and 12 (±28 days) months

Intervention

STRIP is a structured method to perform pharmacotherapy optimisation. This STRIP-intervention consists of 9 steps:

1. structured history taking of medication (SHIM)

2. recording medication and diagnoses in STRIPA

3. structured drug review based on the STRIPA with the integrated STOPP/START criteria

4. communication and discussion of the structured drug review with prescribing physician with possible adaptation of the recommendation

5. shared decision-making with the patient with possible adaptation of the recommendation

6. optional revision based on new accumulating data during hospitalisation (e.g. new diagnoses, adverse drug reactions)

7. generation of GP report

8. delivery of the report to the patient and to the GP (optional additional direct communication)

9. follow-up

A structured questionnaire is used for taking the medication history: Structured History taking of Medication use (SHIM) questionnaire. SHIM will be administered on the bases of the medication which was taken at home and will not consider drugs being administered or stopped during the hospitalization.

The STRIPA is a Dutch software-based tool for the support of the pharmaceutical analysis (step 2 of STRIP) by 1) taking into account the predictable adverse medication effects, 2) advising safe and appropriate therapy using established STOPP/START criteria, 3) interaction monitoring and 4) appropriate dosing in accordance with renal function. It represents a highly efficient and user-friendly software engine capable of individually screening the clinical status and pharmacological therapy of older patients with multimorbidity to define optimal drug therapy and highlight ADR risk.

The STRIPA supported advice provides clinicians with the necessary information for optimising the individual patient’s drug therapy based on a list of clinical data inputs: gender, current medical problems and diagnoses, all medicines that are actually used by the patient according to the SHIM (ATC codes) and dosage, clinical measurements such as heart rate and rhythm, blood pressure, estimated GFR (CKD-epi formula) and other relevant laboratory data. These measurements take about 10 minutes34, and SHIM takes also about 10 minutes28. The STRIPA generates 5 output datasets:

1. potential prescribing omissions of beneficial drugs

2. instances of potentially inappropriate medication

3. presence of ADRs (with use of MedDRA terminology)

4. potential adverse drug interactions

5. dosing advice

Contacts

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Eligibility criteria

Inclusion criteria

Men and women 70 years of age or older Multimorbidity: 3 or more coexistent chronic conditions defined by 3 distinct ICD-10 codes with an estimated duration of 6 months or more. Polypharmacy i.e. five or more different regular drugs (defined as authorised medications with registration numbers) for more than 30 days. Estimated minimal length of stay within the cluster is sufficient to apply the intervention

Exclusion criteria

Inability to provide informed consent or to obtain informed consent from a proxy for patients with cognitive impairment
Direct admission to palliative care (< 24h after admission)
Has passed or will pass a systematic structured drug review during this hospitalisation or within the last two months

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2016
Enrollment:	2000
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47041
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5435
NTR-old	NTR6012
CCMO	NL58279.041.16
OMON	NL-OMON47041

Study results

Summary results
N.A.