# Control in the Hospital by Extensive Clinical rules for Unplanned hospitalisations in elderly Patients.

No registrations found.

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

## Summary

### ID

NL-OMON21393

**Source**
NTR

**Brief title**
CHECkUP

**Health condition**

medication safety; readmission; clinical rules; medication review; CDSS

### Sponsors and support

**Primary sponsor:** Gerontopharmacology, Zuyderland Medical Centre
**Source(s) of monetary or material Support:** ZonMw

### Intervention

### Outcome measures

**Primary outcome**

The primary endpoint is the number of readmissions during the year after admission. An economic evaluation and quality of life analysis is part of the proposal.

**Secondary outcome**

Secondary endpoints of this study are; number of emergency department contacts, number of nursing home admissions during the year after patients' inclusion in the study, death, time to hospital readmission, the number of hospital readmissions during the following 30, 180 and 365 days, the number of medication-related hospital (re) admissions, the combined endpoint hospital readmissions, emergency department contacts, nursing home admissions or death, total costs (from a societal perspective) and the Quality Adjusted Life Years (QALY) score.

# Study description

**Background summary**

Rationale: Hospital readmissions are an indicator of quality of care. To assess whether medication reviews with an extensive set of clinical rules can help to reduce the number of readmissions, we plan to perform a randomized, multicenter, transmural trial comparing medication review with clinical rules versus care as usual.

Objective: The objective is to reduce the number of readmissions in older patients from 20% to 15%. For the Netherlands this may translate into the prevention of 15.600 hospital readmissions per year among patients aged 60 years and over (based on pilot study).
Study design: The study is a prospective multicenter (3 locations) randomized controlled trial with randomization at patient level in intervention and usual care group. In total 1200 patients will be included per group (power 80%; significance level 5%; ICC 0.05; drop-out 20%).

Study population: The study population consists of patients admitted unplanned to the hospital and fulfilling the following criteria: aged 60 years and over, polypharmacy and at least two signals from the trigger list.

Intervention: In the intervention group a structured medication review will be performed by a software program (clinical rule reporter, CRR).

The CRR analyses the patient's characteristics, medication, medical history and lab data. The CRR contains more than 500 different clinical rules. The result of the CRR will be presented to GP/community pharmacist. After discharge the CRR will analyze the medication of the patient each week.

Main study parameters/endpoints: The primary endpoint is the number of readmissions during the year after admission. An economic evaluation and quality of life analysis is part of the proposal. The feasibility of the project is increased as the software is already up and running, the 3 hospital locations form a closed area and the research group has a multidisciplinary character including patients. Based on the calculations we expect to save

between €26.5 and €32.7 M when this intervention is implemented Nationwide.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: With respect to the safety assessment, we would like to emphasize that the CRR is only giving an advice to the physicians and pharmacists, who are primary responsible for the actual care provided to the patients. If the advice is not applicable, the healthcare providers are allowed to ignore the advice. By helping the healthcare providers to remember certain actions which could improve the care for the individual patient, we assume to improve the general care for the individual patient and thereby decrease the chance of readmissions. According to the research group and the consulted patients there is no risk for patients associated with participation in the trial.

### Study objective

By using weekly the clinical rule reporter as the medication review system, the number of hospital readmissions in older patients (> 60 years) will be reduced with 5% (from 20% to 15%). For the Netherlands this may translate into prevention of 15600 hospital readmissions per year among patients aged 60 years and over.

### Study design

readmission, the number of hospital readmissions during the following 30, 180 and 365 days,

Quality of life and economic evaluation: at baseline, after 3, 6 and /or 12 months.

### Intervention

The intervention consists of an extensive medication screening using clinical rules each week

## Contacts

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# Eligibility criteria

## Inclusion criteria

The study population consists of older people admitted unplanned to the hospital and fulfilling the following criteria: 1) aged 60 years and over, 2) ability to give informed consent, 3) polypharmacy (> 5 drugs chronically), 4) at least two signals from the trigger list as proposed by the report "Eindrapport medicatieveiligheid".

## Exclusion criteria

The intention of the study is to include the normal population offered to the hospital as much as possible. However, due to legal constraints and to avoid certain biases potential subjects who meets any of the following criteria will be excluded from participation in this study: intentional intoxications, patients treated with cytostatics, patients with a life expectancy of less than 3 months.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-03-2019 |
| Enrollment: | 2400 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 14-10-2018 |
| 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 | NL7449 |
| NTR-old | NTR7691 |
| CCMO | NLZZ886.096.18 |

## Study results