

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

Published: 29-10-2018

Last updated: 16-11-2024

BACKGROUND/OBJECTIVE 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 randomised, multicenter,...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56177

Source

ToetsingOnline

Brief title

CHECKUP

Condition

- Other condition

Synonym

hospital readmission, polypharmacy

Health condition

polyfarmaciepatienten met verhoogd risico op heropnames

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, DigitalisRx b.v. (software bedrijf clinical rules), 180.000euro aan licenties in natura

Intervention

Keyword: clinical rules, medication review, medication safety, readmission

Outcome measures

Primary outcome

OUTCOME MEASURES

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 $\text{€}26.5$ and $\text{€}32.7$ M when this intervention is implemented Nationwide.

Secondary outcome

nvt

Study description

Background summary

BACKGROUND/OBJECTIVE

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 randomised, multicenter, transmural trial comparing medication review with clinical rules versus care as usual. 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 objective

BACKGROUND/OBJECTIVE

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 randomised, multicenter, transmural trial comparing medication review with clinical rules versus care as usual. 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

STUDY DESIGN

The study is a prospective multicenter (3 locations) randomised controlled trial with randomisation at patient level in intervention and usual care group. 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. In total 1200 patients will be included per group (power 80%; significance level 5%; ICC 0.05; drop-out 20%).

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.

Study burden and risks

Advices are generated towards the physician/ pharmacist. Its up to them to follow up the advices or not. The risk for the patient is therefor minimal.

Contacts

Public

Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL

Scientific

Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

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

-

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	08-03-2019
Enrollment:	2400
Type:	Actual

Ethics review

Approved WMO	
Date:	29-10-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	06-11-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL66886.096.18