Medication (de)prescribing in hospitalized geriatric patients with sarcopenia, less is more?

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The effects of DPA compared to STOPP-START approach (SSA) prescribing on adverse drug reactions, medical complications, hospital readmission, quality of life in hospitalized geriatric patients with sarcopenia

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53702

Source
ToetsingOnline

Brief title
(De)prescribing in hospitalized sarcopenic geriatric patients

Condition

- Other condition
- Gastrointestinal haemorrhages NEC
- Vascular haemorrhagic disorders

Synonym
medication adjustment in older frail hospitalized patients with low muscle strength and muscle mass using at least 5 different medications. (de)prescribing in acutely ill hospitalized sarcopenic geriatric patients with polypharmacy.

Health condition

stoppen/ starten/ dosisaanpassing van medicatie bij acuut zieke sarcopene geriatrische patienten met polyfarmacy en diverse uitgebreide co-morbiditeit waarbij de betrokken

aandoeningen heel divers kunnen zijn en de reden van de medicatie wijziging ook verschillend kan zijn.

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MEDEGESARC

Outcome measures

Primary outcome

number and type of medication stopped during medication review and not

restarted within 1, 3 and 6 months

Secondary outcome

Secondary endpoints: number and severity of Adverse Drug Reactions (ADR) and

complications due to medication (e.g. delirium or falls), hospital readmission,

quality of life (QoL) and mortality

Study description

Background summary

Acutely ill hospitalized geriatric patients have co-morbid disease and polypharmacy and 2/3 have low muscle strength and low muscle mass, called sarcopenic. Although all efforts are done by the multidisciplinary team to combat health problems and negative sequalae of sarcopenia, 80% of the (severely) sarcopenic patients will be deceased within 2 years. Optimalization medication is part of this multidisciplinary treatment strategy. The STOPP-START criteria are applied to optimize the polypharmacy. However, it is not known whether this strategy actually results in a better or worse outcome for these patients. The question that arises is whether it is even better to

minimize pharmacotherapy in these patients and only apply it if the aim is to combat symptoms and complaints and to stop (preventive) medication as much as possible. The latter is called a deprescribing pharmacotherapy approach (DPA) and seemed to be successful in a previous study concerning older frail patients.

Study objective

The effects of DPA compared to STOPP-START approach (SSA) prescribing on adverse drug reactions, medical complications, hospital readmission, quality of life in hospitalized geriatric patients with sarcopenia

Study design

Prospective randomised intervention study. Patients will be randomised in two groups: intervention group (IG) with a DPA of 80 patients and a control group (CG) of 80 patients with a SSA.

Medication review in patients randomised to the IG group will be performed according to the principles of DPA and in the CG this will be performed following the SSA approach.

Intervention

Medication review in patients randomised to the IG group will be performed according to the principles of DPA and in the CG this will be performed following the SSA approach.

Study burden and risks

In either of the two strategies of reviewing medication (SSA or DPA) there are risks for the sarcopenic patients with polypharmacy as part of the usual care. Applying the SSA, which is actually the usual care in the Dutch geriatric ward, there is serious risk of overtreatment with a risk of ADR and complications with holding off benefit because of a necessary time until benefit compared to the limited life expectancy. Although the risk for a ADR is low, a ADR with different kinds of impact can be expected however when starting e.g. preventive medication. But withholding preventative medication as part of DPA can cause a new health problem with minor to major impact if the life expectancy seems longer than predicted and exceeds the time until benefit. Overall, the aim of DPA is to optimize pharmacotherapy and reduce ADR, medication related complications and improve quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

frail older adults, 70 Y and older with sarcopenia and polypharmacy admitted to the acute care hospital ward because of an acute medical problem

Exclusion criteria

If a patient is not instructable. If a patient has an implantable cardioverter defibrillator (ICD) or no informed consent or if there is no (legal) representative with informed consent if the patient is (temporary) incapacitated.

Patients in a palliative phase will be excluded from this study, since most medication will be stopped in a palliative setting.

Finally, patients with an expected admission time of less than 48 hours will be excluded due to logistic reasons (48 hours are needed to screen for suitability, minimum of 24 hours to consider participation).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2023
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-12-2023
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	NL82636.096.22