Unravelling the mechanism behind hospitalization-associated disability in older patients.

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To investigate the physical, psychological, biological and social factors that are associated with hospitalization-associated disability from hospital admission to three months post-discharge in acutely hospitalized older adults.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44968

Source
ToetsingOnline

Brief title
Hospital-ADL study

Condition

- Other condition

Synonym
functional decline., hospitalization-associated disability

Health condition

functionele achteruitgang

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO (ZonNW)

Intervention

Keyword: acute hospitalization, functional decline, hospitalization-associated disability, older patients

Outcome measures

Primary outcome

The primary endpoint will be the disability in activities of daily living

(ADL). We will investigate the underlying mechanism behind

hospitalization-associated disability by testing the physical, psychological,

biological and social factors.

Secondary outcome

Secondary outcomes will be the differences in health care utilization, health

related quality of life, and mortality in older hospitalized patients.

Study description

Background summary

Over 30% of older patients (70 years and above) hospitalized with an acute medical illness show a permanent decline in their ability to maintain basic self-care (i.e., Activities of Daily Living (ADLs), such as bathing, dressing, transferring out of bed, eating, or walking through the house). This problem is denoted as hospitalization-associated disability. Despite the high prevalence of disability after acute hospitalization in older patients, the exact underlying mechanism behind hospitalization-associated disability remains unclear.

Study objective

To investigate the physical, psychological, biological and social factors that

are associated with hospitalization-associated disability from hospital admission to three months post-discharge in acutely hospitalized older adults.

Study design

Longitudinal, prospective, multi-centre, observational cohort study.

Study burden and risks

The underlying physical, psychological, biological and social factors will be analysed. We plan to interview patients five times (admission, discharge, 1-2-3-12 months post-discharge), using questionnaires. We will also perform physical measurements at admission and during hospitalization (walking speed, hand grip strength, muscle mass using bio impedance meter (BIA) and activities performed during hospitalization by a PAM). The first two measure moments, during admission and discharge, will be held in the hospital where the subject is hospitalized. The following follow-ups, at one and three month post discharge will be held at subjects* home. The two follow-ups, at two and twelve months post-discharge, will be held by telephone. The blood samples will be derived from wate products (plasma or serum) of standard venous blood analyses. If waste material cannot be used, four millilitres of blood will be obtainend from the customary laboratory rounds. The risks and burdens in this study are considered to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) acutely admitted to general internal medicine for 48 hours or more;
2) 70 years and older;
3) have approval from the attending Medical Doctor for inclusion;
4) Mini-mental state examination score of 15 or higher (cognitive functioning);
5) able to speak and understand Dutch to complete questionnaires.

Exclusion criteria

1) A life expectancy of three months or less as assessed by the attending MD;
2) Disabled in all six basic ADLs.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2015
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	17-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL54012.018.15

Study results

Date completed:	15-03-2018
Actual enrolment:	401