Triage of Elderly Needing Treatment

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

Summary

ID

NL-OMON54793

Source
ToetsingOnline

Brief title
The TENT-study

Condition

- Other condition

Synonym
Ageing, geriatric screening

Health condition

Veroudering, invasieve therapie en de uitkomsten

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Projectgeld (samenwerking IEMO)

Intervention

Keyword: Aged patients, Geriatric assessment, Invasive treatment, Outcomes

Outcome measures

Primary outcome

Main study end points are:

The following data will be collected from the medical record after the

treatment of the patient is finished:

i) duration of admittance

ii) days on intensive care or medium care

iii) clinical diagnosis of delirium during hospitalization

iv) complications during admittance (infections, falls)

v) unplanned hospital admittance

After a Follow-up of 6 and 12 months after procedure we will collect the

following data by a telephone call:

i) Mortality will be followed through the registry of the municipality (in

Dutch: Gemeentelijke Basis Administratie).

ii) Functional decline by Katz-ADL

iii) Quality of life will be assessed using EuroQOL-5D.

iv) Living arrangement (independent, institutionalized, hospitalized) and level

of support (number of days home-care)

Secondary outcome

not applicable

Study description

Background summary

Aging is accompanied by an increased vulnerability with a consequently higher risk of disease and death. However, older patients are characterized by a high degree of heterogeneity and calendar age alone is a poor marker of individual vulnerability or vitality. A solid measurement of this vitality is especially essential in decision-making in older patients needing invasive treatments like surgery, radiation or chemotherapy.

Conventional geriatric assessment of physical, psychological and social function likely yields valuable predictors, but validated predictors have not been firmly established in the clinical setting. Furthermore, novel makers of biological age and vitality have been identified in various studies (serum biomarkers and measurement of physical activity using accelerometers) and hold great promise, but have sparsely been tested in in the clinical setting.

The Department of Gerontology and Geriatrics of the LUMC has implanted several care pathways on different departments to improve the care for older patients.The geriatric screening is done on those departments and patients are only referred to geriatric doctors in case of abnormalities.

The current study is using the baseline parameters derived from the routine clinical work-up. After a follow-up of 6 and 12 months after procedure we will collect data by reaching out to the patients. Additionally, for this study a blood sample will be collected in context of a WMO-protocol, DNA isloation and for storage. This will be used for future research.

The working hypothesis will be that vulnerable older patients will have worse outcomes in compare with their less vulnerable comparable peers. Besides that we think that geriatric measurements can be an important predictor for the outcomes of treatment.

Study objective

The aim of this study is to see if there is an association between geriatric screening and outcomes. This could lead to a prediction of clinical outcomes in older patients visiting the hospital, using a mix of routine clinical parameters and biomarker-derived measurements.

Study design

For the present study, the data are collected as part of routine clinical practice and additionally 1) follow-up data will be collected from the medical

record regarding the treatment and 6 and 12 months after contacting the patients, 2) baseline blood samples will collected in context of a WMO-protocol and be stored in a biobank for later analysis. 3) a selection of patients will be asked to participate in the resilience study, for which they will carry a wrist band for 12 weeks that measures their physical capacity.

Study burden and risks

After the patient gives informed consent, the extra burden in this study will be drawing of one extra blood sample for purposes of the WMO-protoco inlcuding DNA isolationl and for storage in the *biobank* (mostly in combination with routing clinical blood drawing) and twice contact by telephone, once after 6 months and once after 12 months. The maximum time spent on the extra burden is one hour per participant for the total study.
All other baseline and follow-up data can be collected from the medical record and Municipality Records ("gemeentelijke basis-administratie").

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. Aged 70 years or older at day of presentation or younger than 70 with indication for frailty
2. Indication intention to treat for:
- Malign process in which a treatment (operation, chemotherapy or radiotherapy) is considered
- Vascular disease in which a treatment (operation) is considered
- Benign processes in which a treatment (operation, chemotherapy or radiotherapy) is considered
- Referral to the outpatient department of gerontology and geriatrics for (neuropsychological) screening or any other reason, subjects older than 70 years could also be included when they are considered vulnerable

Exclusion criteria

1. Participant not willing to provide informed consent
2. Participant not able to provide informed consent and no proxy available

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	2180
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-12-2021
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-07-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-06-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28769
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53575.058.15
OMON	NL-OMON28769