Routine clinical care pathway and study in older patients needing intensive treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28769

Source
NTR

Brief title
TENT

Health condition

Any disease needing invasive treatment

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: IEMO

Intervention

Outcome measures

Primary outcome

Mortality, functional decline, quality of life, adverse health outcomes / complications.

Secondary outcome

Mortality, functional decline, quality of life, adverse health outcomes / complications.

Study description

Background summary

Rationale: 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 markers 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.

Objective: The aim is to study the association between geriatric assessment and treatment outcomes in older patients who are candidate for intense treatments for various diseases. 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: A multicenter prospective observational cohort study.

Study population: Patients aged ≥70 years needing invasive treatment.

Study objective

We hypothesize that geriatric screening is helpful in clinical decision making for the older patients needing invasive treatment.

Study design

T0: inclusion, T1: 6 months, T2 12 months.

Intervention

This study is not a clinical trial, no intervention is predefined. We follow the standard care procedures. Next to that, pre-geriatric screening using Geriatric-8 (G8) and the six item cognitive impairment test (6-CIT). In case of abnormalities a comprehensive geriatric assessment will be obtained.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aged 70 years or older at day of presentation
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

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 non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2015
Enrollment:	1640
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Positive opinion

Date:	22-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54793
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8107
CCMO	NL53575.058.15
OMON	NL-OMON54793

Study results

Summary results
None