

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28769

Bron

NTR

Verkorte titel

TENT

Aandoening

Any disease needing invasive treatment

Ondersteuning

Primaire sponsor: LUMC

Overige ondersteuning: IEMO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	1640
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

Not applicable

Ethische beoordeling

Positief advies	
Datum:	22-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54793
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

None