Triage of Reduced Exercise Tolerance in Frail Elderly (TREE).

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The diagnostic triage will be a simple and feasible way to improve the diagnosis and treatment of frail elderly with exercise induced dyspnoea and/or reduced excersie tolerance.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21050

Bron
NTR

Verkorte titel
TREE

Aandoening

Heart failure
Chronic obstructive pulmonary disease
COPD
Hartfalen
Chronisch obstructive longziekte

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Prevalence of latent heart failure and COPD;
2. Difference in prevalence of latent heart failure and COPD between both groups.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Many elderly suffer from reduced exercise tolerance or exercise induced shortness of breath (dyspnoea) which causes decreased mobility and restrictions in physical, psychological and social functioning. Patients commonly attribute this symptom to their age, and simply adjust their life style to it. Reduced exercise tolerance/dyspnoe is very common with prevelance rate of 20-60% of those aged 65 years and over. The main causus in the elderly are heart failure and chronic obstructive pulmonary disease (COPD). Both diseases have a high negative impact on the quality of life and are associated with frequent hospital admissions. Over-diagnosis, but more often under-diagnosis of heart failure and COPD is rather common in primary care. Establishing a diagnosis early in the course of the disease is useful because both diseases can be adequately and evidence-based treated. Therefore, an easy diagnostic triage-strategy followed bij direct treatment would be of great importance to asses and treat heart failure and COPD in elderly patient with shortness of breath.

Objective of the study:

Quantify how many frail elderly aged over 65 years with reduced exercise tolerance and/or exercise induced dyspnoea have previously unrecognised COPD and heart failure. Quantify the difference in prevalence of unrecognised COPD and heart failure between those who underwent the diagnostic triage compared to those who received care as usual. Quantify the effect of the diagnostic triage plus the additionally treatment changes on functionality and quality of life after 6 months compared to those who received care as usual. Quantify the cost-effectiveness of the diagnostic triage strategy compared to care as usual.

Study design:

A clustered randomized diagnostic (follow-up) study.

Study population:

First, pre-selection of patients aged over 65 years from 50 general practices is based on frailty. Frailty is based on the next criteria: use 5 or more different types of medical drugs chronically in the last year and/or have 3 or more chronic or vitality threating diseases (such as diabetes mellitus, COPD, heart failure, impaired vision, hard hearingness). This will be done from the electronic medical files of the general practices. These elderly will receive the MRC questionnaire of dyspnoea and three additional questions related tot exercise intolerance. Those with any dyspnoea and/or reduced exercise tolerance will be invited to participate, except those with established heart failure and COPD.

Study parameters/outcome of the study:

Prevalence of latent heart failure and COPD. Difference in prevalence of latent heart failure and COPD between both groups. Differences in functionality and quality of life after 6 months between both groups. Cost-effectiveness and experienced patient burden of the diagnostic triage strategy.

Doel van het onderzoek

The diagnostic triage will be a simple and feasible way to improve the diagnosis and treatment of frail elderly with exercise induced dyspnoea and/or reduced excersie tolerance.

Onderzoeksopzet

Primary outcomes will be meassured at one time point. Secudary outcomes will be meassured in two time points (in the beginning of the study and after six months).

Onderzoeksproduct en/of interventie

1. Diagnostic triage strategy (index group) including; electrocardiography, echocardiography, spirmetry and blood testing;

2. Care-as-usual (control group).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged 65 years and older;

2. Must have a minimum of three chronic or vitality threatening diseases and/or use five or more medical drugs chronically in the last year;

3. Must have dyspnea and/or reduced exercise tolerance (scored by two short questionnaires).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with both confirmed COPD and heart failure (lungfunction test performed < 1 year ago and heart failure confirmed by echocardiography);

2. Patients unable or unwilling to sign informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2212
NTR-old	NTR2336
Ander register	ZonMW : 311040302
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A