Strategy to recognize and initiate treatment of chronic heart failure (STRETCH).

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A structured diagnostic-therapeutic strategy to detect and treat previously unrecognized (or unestablished) heart failure in primary care will improve the quality of care, the quality of life, and eventually the prognosis of these patients.

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

Samenvatting

ID

NL-OMON20397

Bron
NTR

Verkorte titel
STRETCH

Aandoening

Heart failure

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: Nederlandse Hartstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of the diagnostic part of our combined diagnostic-therapeutic strategy is:
1. Prevalence of 'systolic' and 'diastolic' heart failure in elderly who presented to the general practitioner with shortness of breath on exertion.

The primary outcomes of the therapeutic part of our combined diagnostic-therapeutic strategy are:
1. Differences in prescription of ACE-inhibitors and beta-blockers between the intervention and control group after 6 months follow-up;
2. Differences in quality of life between patients in the two groups after 6 months follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Heart failure is an emerging epidemic in especially the elderly, with high mortality rates, substantial loss in quality of life, and high healthcare costs, mainly due to hospitalizations. The majority of (usually elderly) patients with heart failure are diagnosed and managed in primary care. However underdiagnosis and undertreatment of patients with heart failure in primary care are common. Implementation of a standardized diagnostic protocol together with educating general practitioners in a pragmatic treatment strategy in which the focus lays on uptitration of heartfailure medication, would fill the gap of underdiagnosis and undertreatment that nowadays exists in primary care.

Objective:

To determine the effect of a structured diagnostic-therapeutic strategy to detect and treat previously unrecognized or unestablished heart failure in primary care as compared to care as usual.

Study design:

Combination of a diagnostic implementation study and cluster randomized trial in primary care.

Methods:

All participants will undergo a standardized diagnostic work-up to establish or rule out heart failure. In those participants with an abnormal ECG and/or elevated natriuretic peptide level additional echocardiography will be performed at the outpatient clinic of the Diakonessenhuis in Zeist. The definite diagnosis of heart failure ('systolic' or 'diastolic') will be established by an expert panel consisting of two cardiologists and a general practitioner. The panel will apply the criteria of the updated heart failure guidelines (2008) of the European Society of Cardiology (ESC). Patients with heart failure will subsequently be treated by their own general practitioner. The participating general practitioners will be randomly divided into either care as usual (control group) or special up-titration (intervention group). Both groups will be using medication as recommended in the Dutch heart failure standard. However, general practitioners in the intervention group will be especially trained in the practical appliance of this guideline: the initiation of diuretics and ACE-inhibitors and structured up-titration of ACE-inhibitors and beta-blockers. In the training, practical examples will be used concerning barriers the general practitioners themselves encountered when using this medication. In the intervention group, patients with 'systolic' heart failure will receive the recommended maximal dose or the highest tolerated dose. Patients with 'diastolic' heart failure will receive optimal blood pressure and heart rate control with the preferred cardiovascular drugs. At baseline and six months after heart failure is established or ruled out, all participants fill out quality of life questionnaires. During those six months, only participants with heart failure will additionally fill out one of these questionnaires every three weeks. Also after six months, electronical files of the general practitioners will be scruntinized to assess the (dosage of) prescribed medication.

Doel van het onderzoek

A structured diagnostic-therapeutic strategy to detect and treat previously unrecognized (or unestablished) heart failure in primary care will improve the quality of care, the quality of life, and eventually the prognosis of these patients.

Onderzoeksopzet

Outcomes will be meassured in two time points; in the beginning of the study and after six months of follow-up.

Onderzoeksproduct en/of interventie

Training of general practitioners in up-titration of heart failure medication. General practitioners in the intervention group will receive a single training of 2 hours from a cardiologist. The uptitrationschema of ACE-inhibitors and betablockers (based on the newest version of the NHG-standard 'Heartfailure') will be discussed and considered are the unwanted effects, interactions and contra-indications. Practical examples are being used.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 65 years or over;

2. Shortness of breath as reason for GP contact in the previous 12 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Already established heart failure, that is a diagnosis of heart failure confirmed by the cardiologist with echocardiography;

2. A life expectancy shorter than 6 months;

3. Not being able to give informed consent.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Gerandomiseerd

Blindering: Enkelblind

Controle: Geneesmiddel

Deelname

Nederland
Status: Werving nog niet gestart

(Verwachte) startdatum: 01-10-2010

Aantal proefpersonen: 1500

Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 01-09-2010

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	NL2383
NTR-old	NTR2490
Ander register	Nederlandse Hartstichting : 2009B048
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A