The Chronic Heartfailure Prevention Project

Published: 02-04-2012
Last updated: 26-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON37619

Source
ToetsingOnline

Brief title
CHEAP

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Heart failure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: PoZoB
Source(s) of monetary or material Support: Stichting Beloce

Intervention

Keyword: Heart failure, Hypertension, Prevention, Screening

Outcome measures

Primary outcome

To define a set of determinants which can be associated with hypertensive

patients in Primary Care who are at risk for developing heart failure.

Secondary outcome

The effect of depression, anxiety and type D personality on quality of life of

hypertensive patients in Primary Care.

Study description

Background summary

Chronic Heart Failure (CHF) is a chronic heart condition in which the heart pump is unable to meet the demands for adequate circulation of the blood. CHF is a common disorder. In The Netherlands 1% of the general population suffers of CHF which currently refers to 159.000 people. Depending on age, the year prevalence increases from 3/1000 in people between 15 - 64 years of age to 86/1000 in people over 65 years. In the next three decades, the number of aging people will dramatically increase: by 2040, 4.6 million people (one third of the total population) will be over 65. This means that the number of patients with CHF will also increase (there are estimates that the absolute number of people with CHF between 2005 and 2025 will increase by 46.9%).

In general, the level of symptoms in CHF are defined by the New-York Heart Association criteria (NYHA classes I - IV). In class I, there are no signs and symptoms during normal physical exercise. In class II, there are no signs and symptoms when resting but normal physical exercise results in symptoms of fatigue and chest pain. In class III, there are no symptoms at rest, but any minimal physical exercise provokes serious symptoms. In class IV, there are signs and symptoms at rest, any (minimal) physical activity results in increasing symptoms.
CHF is a serious condition. In patients with CHF the mortality rate is 37% < 1 year, 49% < 2 years and 65% < 5 years after diagnosis. Annually, in our country, approximately 6900 patients die because of CHF, which is 18% of total

deaths because of heart disease. Moreover, another 25.000 patients are hospitalized which means that about 20% (31.900/159.000) of all patients suffering from CHF annually passes through a major event because of CHF (death or hospitalization). In 2005, the direct health costs because of CHF were estimated on 387.5 million euro, which is 1% of total health costs in the Netherlands and 7% of total costs because of heart disease in general. Apart from direct signs and symptoms of CHF, many patients suffer from decreased quality of life. Because of symptoms at minimal exercise, many patients stay at home, most of the time seated in a chair, and are unable to have social contacts. Depression because of loneliness is very common in CHF patients. Moreover, high levels of anxiety exist because of fear of an exacerbation of symptoms, often resulting in hospitalization and higher mortality.

In general, two different classes of CHF can be discriminated: systolic and diastolic CHF. In the first category, decreased contractility of the heart muscle is the main reason of heart failure most often caused by ischemic heart disease or cardiomyopathy. In diastolic heart failure, there is a decreased left ventricular filling most often caused by decreased relaxation of the ventricular muscle because of hypertrophy or fibrotic processes. The distinction between the two classes of heart failure is not absolute and often diastolic HF proceeds systolic HF, like in ischemic disease and hypertension. Therefore, the recent CBO guidelines report a distinction between HF with normal ventricular ejection fraction (VEF > 50%) and HF with a decreased VEF (< 50%).

An important cause of CHF is hypertension. Because of chronic increased tension, there is at first a decreased left ventricular filling hardly affecting the contractility (diastolic HF). However, after years, this is followed by a dilatation of the left ventricle with decreased contractility (systolic HF). As a consequence of increased intravascular volume, the ventricular muscle produces brain natriuretic peptide (BNP) which tries to compensate the overfilling by increasing natriurese and vasodilatation. Increased levels of BNP can be a first manifestation of HF.
Hypertension (HT) is very common in Primary Care (PC). In the general population, in men between 20 and 60 years of age one out of four has hypertension (>= 140/90 mmHg), which is one out of five in women of similar age. In men over 65 years of age, 38% has hypertension compared to 42% of the women. During the last decade, once the diagnosis of HT has been confirmed and no secondary causes have been demonstrated, most of the HT patients in PC are treated by a PC practice nurse. Until now, there are no data on the prevalence of CHF in **asymptomatic** or **stable** HT patients in Primary Care.

A major public health issue is the underestimation of CHF in the general population. Many patients with (early stages of) CHF do not visit their GP to complain about signs and symptoms possible related to CHF but rather consult for regular check-ups of blood pressure, cholesterol, diabetes parameters e.g. However, the GP can assess BNP in patients at risk for HF and more recently has

access to echocardiogram*s (EC). EC is a non-invasive patient friendly method to detect early signs of abnormal structural and / or functional heart activity at rest that are prognostic factors for developing HF.
The consequences of inappropriate diagnosis and treatment of CHF are substantial. Once a patient is in class III and class IV, apart from death, many patients need frequent hospitalizations and a substantial part of them are referred to nursing homes. Until now, the reliability (sensitivity, specificity, positive predictive value) of BNP and EC assessments in **asymptomatic** HT patients in PC to predict the development of future HF is not known. Therefore, the main topic of CHEAP is to evaluate whether there are adequate tools for the GP to detect patients at risk for developing future HF.

Study objective

The mission of CHEAP is to evaluate whether a protocol can be developed that enables the GP to detect patients with primary hypertension who are at risk for developing future heart failure.
The European Society of Cardiology has recently (2008) defined three different categories of HF.
(1) Newly developed HF: first manifestation of acute HF
(2) Temporary HF: HF that disappears over time such as in myocarditis
(3) Chronic HF: irreversible HF that can be stable, progressive or an exacerbation.
Within CHEAP, determinants of category I and III in a population at risk to develop HF will be investigated.

Primary outcome of CHEAP is:
At a cross-sectional level
1. Is it possible to define a profile of HT patients in Primary Care who are at risk of developing HF, with regard to:
Signs and symptoms
Assessment of BNP
Assessment of ECG
Assessment of EC
2. What is the outcome of screening of Primary Care HT patients with assessment of signs and symptoms, BNP, ECG and EC with regard to:
Diagnosis of chronic heart failure
Medication
Referral to secondary care
Follow-up
At a prospective level:
3. Does intervention in Primary Care HT patients at risk to develop future HF benefit in term of risk reduction?

Secondary outcome of CHEAP is:
At cross-sectional level

1. Do Primary Care HT patients with a high risk profile of HF differ from those with low profile in terms of quality of life?
2. Is there a difference in depression and anxiety levels between Primary Care HT patients with and without a high risk profile of HF?
At a prospective level
1. Does intervention in patients with a high risk profile of HF contribute to better quality of life?
2. Does intervention in patients with a high risk profile of HF interfere with levels of depression and anxiety?

Study design

HT Patients between 60-85 years who meet the inclusion criteria will be selected by the central data administration of PoZoB after informed consent of their GP. The GP will check the list on exclusion criteria. Eligible patients will receive written information by mail. Within three weeks, they will be contacted by phone whether they agree to participate. The participants will have an appointment at the GP office and sign an informed consent. They will have an interview of 45 - 60 minutes during which questionnaires regarding medical history, signs and symptoms of HF, quality of life and symptoms of depression and anxiety will be assessed. Moreover, the blood pressure will be assessed twice, as well as BMI and waist circumference. After the intake, a second appointment will be planned at the GP office for blood assessment, an echocardiogram and an electrocardiogram.

All data will be evaluated by an independent cardiologist, who will advise the GP about the outcome. The GP will receive a written summary. Besides, the GP will be offered to discuss the outcome of the screening during an appointment with the independent cardiologist.
After the screening, all patients who give informed consent will be followed by questionnaires at 6,12, 18 and 24 months. Moreover, the biological outcome parameters of the HT patients within the CVRM POZOB program will be followed.

Study burden and risks

The risks for the participants are considered minimal. The progression of heart failure of patients at risk often goes unnoticed. Given the impact of serious harftalen and given the fact that early intervention (medication adjustment en possibly surgery in severe valvular heart disease) prevents further progression, it is to justify that a relatively patient friendly intervention (venipuncture, cardiac echo and ECG) is performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Primary care patients aged between 60-85 years with diagnosed hypertension (ICPC K86 and/or K87 in the patient file)

Exclusion criteria

diagnosis of heart failure
being currently treated by a cardiologist
recently had a echocardiogram
cognitive impairments (e.g. dementia)
a current history of severe psychiatric illness other than mood or anxiety disorder
terminal illness
insufficient skills of the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2012
Enrollment:	500
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	02-04-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL38933.008.12