Heart Failure clinics versus primary care in the long-term follow-up of patients with chronic heart failure; COACH-2

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON36913

Source
ToetsingOnline

Brief title
Long term care for Heart Failure patients; HF clinics versus primary care

Condition

- Heart failures

Synonym
chronic heart failure, venticular dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: guideline adherence, heart failure, long term, primary care

Outcome measures

Primary outcome

Primary endpoint is medication use.

- Guideline adherence defined as prescription of medication.

- Patient compliance with medication

Secondary outcome

Secundary endpoints;

- guideline adherence medication optimal dose

- patient compliance regarding diet, fluid restriction and weighing

- number and duration of readmissions for heart failure

- mortality

- (NTpro)BNP

- quality of life

- patient/partner satisfaction with care

Study description

Background summary

Multidisciplinary management programs within specialized HF clinics have proven to be effective in terms of patient compliance, hospital readmission and mortality. Most of the programs implemented in the Netherlands focus on hospital based (outpatient) care, primary care by means of General Practitioners (GP) or specialized HF nurses are involved in only a minority of the programs in the Netherlands.
Since the prevalence of HF is still growing, it is now foreseen that the HF clinics will become overloaded and will not be able to -after initial

management of new patients, treat and monitor all HF patients for longer time periods. However, it is known that long term follow-up is vital since studies have shown that the results of initial optimization of therapy and education (guideline adherence and patient compliance) will decrease within the next year, in case no appropriate follow-up is provided. Ideally, long term follow-up should be incorporated within the primary health care system. However, at this time it is unclear whether and when patients can be discharged from the HF clinic to be further managed in primary care.

Study objective

The aim of the current study is to determine whether long-term follow-up in primary care, under the condition of initial optimization of pharmacological and non-pharmacological treatment at the specialized HF clinic is equally effective as long term follow up at the specialized HF clinic in terms of guideline adherence, patient compliance in patients with heart failure.

Study design

Within the current study patients will be discharged from the heart failure clinic to primary care under the following conditions; (1) patients are in a stable condition, (2) patients are optimally up-titrated on medication (according to the Dutch Multidisciplinary Guideline Chronic Heart Failure), (3) patients have received optimal education and counselling on pre-specified issues. Furthermore, close cooperation between secondary and primary care in terms of back referral to or consultation of the HF clinic will be provided as it is an important condition to facilitate optimal follow-up (conform the Dutch Multidisciplinary Guideline Chronic Heart Failure).
The study objective will be addressed by using the design of a Randomized Controlled Trial. In total 200 patients will be randomly assigned to follow-up in primary care or to follow-up by the heart failure clinic. Data will be collected at baseline and after a 12 months follow-up period. Additionally, descriptive data will be collected at 18 months on limited parameters and the natural conduct of care after disconnection from the randomization.

Intervention

The intervention consists of follow-up care during 12 month by either primary care (GP and specialized nurs) or the heart failure clinic. Both will use the same national guideline

Study burden and risks

Patients in both study groups will receive care following the Dutch Multidisciplinary Guideline on Chronic Heart Failure. Therefore there are no risks involved for patients participating in the study.

The burden for patients consists of 2 assessments; at baseline and at the end of the study. Patients will be asked to fill in questionnaires (20 minutes) and blood samples will be taken during routine (according to the national guideline) blood punctures. The end of study assessment will take place within the HF clinic, an appointment will be scheduled.
Participating patients will also be asked to fill in a weight diary for a period of 4 weeks. Also partner of patients (if available) will be asked to fill in a questionnaire.

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

- patients having treated symptomatic, systolic Heart Failure with evidence for structural underlying ventricular dysfunction (LVEF<45% at the time of diagnosis),

- patient is up-titrated to optimal medication (according to the Dutch Multidisciplinary Guideline on Chronic Heart Failure, 2002/2009)
- patient is optimally informed and educated about heart failure, its treatment and lifestyle changes
- patients in a stable condition; no readmissions, no visits at the emergency unit, no unplanned medication changes in the previous month (and for maximally 2 years)

Exclusion criteria

- patient management by a cardiologist planned for diagnostics or treatment is needed
- the GP has substantial arguments agaist patient participation in the study
- restrictions that render patients to fill in data collection materials
- life expectance shorter than 6 months
- patient is living in a nursing home
- current psychiatric disorder as documented in the medical record

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	13-02-2009
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL25474.042.08