DEventer-ALkmaar Heart failure Project.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24472

Source
NTR

Brief title
DEAL-HF

Sponsors and support

Primary sponsor: Funding/Support: This study was financially supported by a grant from Novartis Pharma BV, AstraZeneca BV, Bristol-Myers Squibb BV. Roche Diagnostics provided the test essays for NT-proBNP.

Role of sponsors: The funding source for this study played no role in the design or conduct of the study; data management and analysis; or manuscript preparation, review, and authorisation for submission.

Intervention

Outcome measures

Primary outcome

The primary endpoint was the composite of hospitalisation for worsening HF and/or all cause mortality. Further, the effect on LVEF, NYHA class, quality of life, NT-proBNP, and self-care behaviour was assessed.

Secondary outcome

Additional endpoints included time to (HF) hospitalization or death, utilisation of HF medication and costs of care.

Study description

Background summary

Conclusion: We showed that a heart failure clinic involving an intensive, protocolised intervention by both a clinician and a cardiovascular nurse, substantially reduces hospitalisations for worsening HF and/or all cause mortality and improves functional status, while decreasing health care costs, even in a country with a primary care-based health care system.

Study objective

To determine whether a regular and protocolised intervention at a heart failure (HF) clinic by a combination of a clinician and a cardiovascular nurse, both trained in HF, reduces hospitalisation for worsening HF and/or all cause mortality and improves functional status (including left ventricular ejection fraction, NYHA class and quality of life) in patients with NYHA class III or IV HF.

Study design

N/A

Intervention

Methods:

240 patients were randomly allocated to the 1-year intervention (n=118) or usual care (n=122). The intervention consisted of nine visits with increasing intervals to a combined, intensive physician-and-nurse-directed HF outpatient clinic, starting a week after hospital discharge or referral from the outpatient clinic. Verbal and written comprehensive education, optimisation of treatment, easy access to the clinic, recommendations for exercise and rest, and advice for symptom monitoring and self care were provided. Usual care included non-protocolised outpatient visits initialised by individual cardiologists in the cardiology departments involved.

Contacts

Public

Deventer Hospital, Department of Cardiology,
Fesefurstraat 7
Pieta W.F. Bruggink - André de la Porte
Fesefurstraat 7
Deventer 7415 CM
The Netherlands
+31 (0)570 646710
Scientific
Deventer Hospital, Department of Cardiology,
Fesefurstraat 7
Pieta W.F. Bruggink - André de la Porte
Fesefurstraat 7
Deventer 7415 CM
The Netherlands
+31 (0)570 646710

Eligibility criteria

Inclusion criteria

The following are required at screening visit:

1. In – or out hospital patients with congestive heart failure New York Heart Association Functional Class III and IV;

2. Diagnosis of heart failure established definitely by typical clinical signs and symptoms of heart failure in conjunction with radiographic and / or echocardiographic findings of a reduced ventricular function, according to the guidelines for the diagnosis of heart failure of the European Society of Cardiology.
Symptoms of heartfailure and systolic dysfunction NYHA III / IV and Left Ventricular Ejection Fraction <=45%
or
Symptoms of heart failure and diastolic dysfunction NYHA III/ IV;

3. Signed informed consent.

Exclusion criteria

1. Severe dementia or serious psychiatric illness;

2. Discharge to a nursing home;

3. Disease other than CHF with an expected survival of less than one year (terminal illness);

4. Participation in another study;

5. Planned hospitalisation or ongoing hospitalisation;

6. Patient receiving kidney function replacement therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2000
Enrollment:	240
Type:	Actual

Ethics review

Positive opinion

Date:	10-02-2006
Application type:	First submission

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
NTR-new	NL548
NTR-old	NTR603
Other	: N/A
ISRCTN	Incomplete info ISRCTN

Study results

Summary results
Bruggink-Andre de la Porte PW, Lok DJ, van Wijngaarden J, Cornel JH, Pruijsers-Lamers D, van Veldhuisen DJ, Hoes AW. Related Articles, Links.
Heart failure programmes in countries with a primary care-based health care system. Are additional trials necessary? Design of the DEAL-HF study.
Eur J Heart Fail. 2005 Aug;7(5):910-20. Review.
PMID: 16087143 [PubMed - indexed for MEDLINE].