DEventer-ALkmaar Heart failure Project.

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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...

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

Samenvatting

ID

NL-OMON24472

Bron
NTR

Verkorte titel
DEAL-HF

Ondersteuning

Primaire 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

Deventer Hospital, Department of Cardiology,
Fesefurstraat 7
Pieta W.F. Bruggink - André de la Porte
Fesefurstraat 7
Deventer 7415 CM
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2000
Aantal proefpersonen:	240
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-02-2006
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	NL548
NTR-old	NTR603
Ander register	: N/A
ISRCTN	Incomplete info ISRCTN

Resultaten

Samenvatting resultaten
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].