Fragility in older people with decompensated heart failure

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29310

Source
Nationaal Trial Register

Brief title
TWENTE-HF1

Health condition

Heart failure

Sponsors and support

Primary sponsor: ZGT (Hospital Group Twente), Almelo and Hengelo, The Netherlands
Source(s) of monetary or material Support: ZGT (Hospital Group Twente), Almelo and Hengelo, The Netherlands

Intervention

Outcome measures

Primary outcome

Observational study: quality of life (Minnesota Living with Heart Failure Questionnaire (MLHFQ). and abilities of self-care (European Heart Failure Self-care Behaviour Scale)

Secondary outcome

Observational study: rehospitalization for heart failure during one year of follow-up.

Study description

Background summary

Background: Despite great progress in the areas of knowledge, prevention, research, treatment and counseling of patients with chronic heart failure, there is still a high burden of disease and premature death. Heart failure can occur at all ages, but is a prevalent condition in the elderly, with various comorbidities. In the case of frail older people, heart failure can have an even greater influence on decreased quality of life, re-hospitalization and mortality.
Objective: a. Determining and measuring fragility by means of score lists, in relation to characteristics of heart failure, during and after hospitalization in ZGT (Hospital Group Twente, Almelo and Hengelo, The Netherlands), due to decompensated heart failure. b. Risk stratification for deterioration in functional and cognitive functions, decrease in self-care capacity after hospitalization for decompensated heart failure.
Study design: An explorative, prospective, observational cohort study, in one center (ZGT).
Study population: Patients with heart failure who are 70 years of age or older, admitted to the Cardiology Department of ZGT, for treatment of decompensated heart failure. A total of 50 patients will participate in the study.
Main study parameters: During hospital admission, standard blood is taken as part of regular patient care to check for kidney function, electrolytes and NT-proBNP. Patients are asked to complete questionnaires about HF and self-care. They are also asked to undergo geriatric and cognitive function tests. Various related scores are determined. These form a basis for the degree of fragility. The course after dismissal can also be analyzed.
Patient burden: Completing the questionnaires takes approximately 20 minutes. The geriatric and cognitive function tests last approximately 1 hour. The physical tests (duration around 30 minutes) are placed under the physioconsult standard care.
Participation is voluntary and there are no risks associated with the research. Patients can stop participating in the study at any time during the study without giving a reason and without consequences for further treatment and care.

Public summary: Heart failure is a disease with a high disease burden that occurs in more than 10% of people over seventy in the Netherlands. Most have multiple diseases and use many different drugs, which makes heart failure care complex. Specific guidance in the clinic and in a heart failure outpatient clinic can improve disease insight and therapy compliance (self-care). Seventy people with heart failure with increased heart failure and mental and / or physical decline often occur in people over the age of seventy. This can have a negative impact on their self-care and there is more chance of heart failure being disrupted.
To determine the extent of vulnerability, self-care, quality of life, the goal of our study, in 50 elderly patients admitted to the Cardiology nursing ward of ZGT, for treatment of decompensated heart failure, the degree of vulnerability, self-care. We also investigate the mutual influences of these aspects and what the chance is of hospitalization. Participation is voluntary and there are no risks involved.

Study objective

The frailty syndrome negatively impacts quality of life, morbidity and mortality of older people with decompensated heart failure and during follow-up after hospital discharge.

Study design

Baseline (just prior to hospital discharge for heart failure), and after 3, 6 and 12 months.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Admission for decompensated heart failure (systolic or diastolic) with underlying heart disease, diagnosed by the cardiologist
2. Age >= 70 years
3. Being able to read and write Dutch
4. Written informed consent obtained

Exclusion criteria

1. Patients who were previously admitted to an institution for elderly care or nursing home or hospice
2. Patients included in a study medication trial
3. Patients who have had heart surgery or other major surgery or surgery in the previous 4 weeks
4. Patients on the waiting list for heart transplantation or heart pump (LV assist device)
5. Patients undergoing kidney dialysis
6. Patients with moderate to severe dementia
7. Patients for whom an abstinent policy has been chosen

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL8441
Other	Advisory committee Medisch Spectrum Twente at Enschede, the Netherlands : K20-12

Study results