Prevalence, diagnosis and management of heart failure in nursing home residents

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

Summary

ID

NL-OMON34256

Source
ToetsingOnline

Brief title
heart failure in nursing homes

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: heart failure, nursing home, prevalence, quality of life

Outcome measures

Primary outcome

* The prevalence of heart failure in Dutch Nursing homes

* The predictive value to diagnose heart failure in a nursing home without using echocardiography as golden standard

* The current treatment of heart failure in nursing homes compared to national guidelines

* The care dependency and quality of life of nursing home residents with heart failure compared to them with no heart failure,

* Insight in the course of heart failure after one year follow-up with the outcomes: heart failure events, hospital admissions for heart failure and mortality.

Secondary outcome

not applicable

Study description

Background summary

Heart failure is an increasing clinical problem in western countries and particularly a disease of the elderly. The prevalence and incidence of heart failure are expected to increase within the near future, because of the higher survival rates for myocardial infarction and cerebrovascular diseases. In western countries the prevalence of heart failure in the community ranges from 3-13% for those aged over 65 years. In the Netherlands the prevalence of heart failure in the general population is estimated at 13% in persons of 75 or older. Heart failure is characterized by a poor prognosis and quality of life. It is

known that early diagnosis and treatment may prevent progression of heart failure and lead to improvement of symptoms and quality of life.
Most of the older persons over 65 years live independently in their own homes and only a small proportion live in special institutions for chronic care (residential care and nursing homes). The older persons in nursing homes are mostly the frail elderly representing a specific patient group. They show high levels of care dependency because of their disabillities, resulting from their multimorbidity. Heart failure is expected to be particularly prevalent in the nursing home population but reliable data about heart failure in nursing homes in general and in the Netherlands in particular, are lacking. The most important reason for this is that nursing home residents are often not included in clinical and epidemiological studies.
A recent literature study on the prevalence of heart failure in nursing homes confirmed that studies on the prevalence of heart failure are lacking and has emphasized the need for research on the prevalence of heart failure in this environment. Data from the few included studies reveal a prevalence of heart failure in this vulnerable population of about 20% (range 15-45%); a figure that indeed is higher than in the general population (3-13%). However most studies included in the review, used a retrospectiv design and consisted of gathering data from patient records instead of actually diagnosing the disease by concrete examination. There was one small study in wich residents were diagnosed after concrete clinical examination and this study demonstrated a prevalence of heart failure of 45%.
Because of the fact that, the improvement of symptoms and quality of life are very important aspects of the care for nursing home residents, it is very relevant to know more about the problem of heart failure in this specific group of elderly; especially because literature reveals that there is still a lot to do in long-term care settings to improve care for residents with heart failure.

Study objective

The objective of the current study is:
- to enlarge the knowledge of the prevalence of heart failure and its management of nursing home residents with heart failure.
- to get insight into the care dependency and quality of life of nursing home residents with heart failure.
- to optimize the diagnostic proces and treatment of heart failure in nursing homes

This objective has resulted in the following research questions:
1. What is the prevalence of HF in nursing homes in the southern part of the Netherlands for both somatic and psychogeriatric residents ?
2. What are the characteristics (such as demographics, cognitive status, cardiovascular risk factors and history) of nursing home residents with heart failure?
3. How is HF currently treated pharmacologically and non-pharmacologically in

Dutch nursing homes?
4. What is the relation between heart failure and respectively the care dependency and quality of life of nursing home residents in both somatic and psychogeriatric residents?
5. What is the predictive value of an onsite assessment (or elements) of heart failure in nursing home residents using a clinical assessment (history, physical examination, ECG and NT-pro BNP) in the nursing home versus the golden standard of an overall judgement of this assessment by a panel of cardiologists, including additional echocardiography?
6. How is the course of heart failure in nursing home residents after 1-year follow-up with outcomes of: heart failure events, hospital admissions for heart failure and mortality?
7. How is the course in care dependency and quality of life look like among patients with heart failure in comparison to those with no heart failure after 1-year follow-up?

Study design

For this study a multi-centre cross-sectional design will be used.
After informed consent the specially trained nursing home physicians starts to examine the included participants by performing the history and physical examination. An electrocardiography is made and a venous bloodsample is taken to determine the NT-pro BNP value (5ml). An echocardiographist will perform the echocardiography with a mobile echo device.
The research assistant and the NHP/researcher are responsible for gathering the data from the medical records, the questionnaires, to perform the ECG and the measurement of the NT-pro BNP marker.
After one year data are gathered from the medical records regarding any heart failure events, hospital admission for haertfailure and mortality.

Study burden and risks

The clinical examinations including a blood sample, ECG and an echocardiography are conducted conform the accepted guidelines and is regular medical care. All the examinations take place in the nursing homes. Complementary data are gathered from the medical records and questionnairies (SF-12, Qualidem, MDS, MMSE). In two weeks time all parts of the examinations are performed at a time that has the accordance of the resident and/or the nursing staff.
The burden of the examinations probably might be the time- investment and for some residents the blood sample that is taken.
There are no special risks for participating nursing home residents.
In the pilot study (The prevalence of heart failure in a nursing home; a pilot study NL 23691.068.08), that anticipates on this study, included residents experienced the participation as a "pleasant" variance of their daily activities. An important detail is that appoinments should be made in accordance with the residents and/or nursing staff, so there is no interference

with the personal care and the use of meals.
The burden for the psychogeriatric residents is more difficult to estimate. Besides the bloodsample that is taken, probably the performance of the echogardiography will be experienced as a burden.
From the TIME-CHF study (2006) , where also residents with cognitive impairment were included, it is known that when the echocardiogram takes more than 20 minutes agitation might arise. In the pilot all the echocardiographies were finished within 20 minutes. By presence of two persons at time of the echogardiography there will be enough attention for the residence as turned out in the pilot and will prevent an uncomfortable feeling about the examination. Attentiveness on any kind of resistance against the examinations in psychogeriatric residents remains necessary.

In Dutch nursing homes residents are living on a somatic ward when they suffer from disabillities and functional loss because of their somatic illnesses and on a psychogeriatric ward if they suffer from severe cognitive impairments or dementia. However, in real life there is not always a sharp distinction caused by the fact that some somatic diseases are accompanied by cognitive impairment (such as M. parkinson or in cerebrovascular accidents).
For the purpose of this study we intend to investigate nursing home residents of both groups. An important reason to include residents with dementia or cognitive impairment in this study is evidenced by the fact that cerebral blood flow may decrease due to heart failure resulting in further worsening of the cognitive impairments. It is expected that adequate treatment will improve the cognitive impairment and probably due to this also the quality of life.
Heart failure is expected to be prevalent in nursing home residents. The performance of this study may lead to the benefit that an unknown heart failure resident is detected. If so, adequate treatment for heart failure can be started which may lead to a better prognosis and improvement of quality of life.
In addition by including both groups of nursing home residents we can research if there is a difference in prevalence, diagnosis, management and care dependency due to heart failure.

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

nursing home residents aged over 65 years and staying on somatic or psychogeriatric wards.

Exclusion criteria

residents who receive palliative care and residents admitted for short-time rehabilitation (staying < 2 months).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2011
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	27-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-05-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL33281.068.10