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Impact of multi-disciplinary treatment strategy on systolic heart failure outcome

Submission date
24/09/2019

Recruitment status
No longer recruiting

Registration date
25/09/2019

Overall study status
Completed

Last Edited
09/06/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with reduced ejection fraction have high rates of mortality and readmission after hospitalization for heart failure. In Taiwan, heart failure disease management programs (HFDMPs) have proven effective for reducing readmissions for decompensated heart failure or other cardiovascular causes by up to 30%. However, the benefits of HFDMP in different populations of heart failure patients is unknown.

Who can participate?
Patients admitted for systolic heart failure with reduced EF radiographic evidence of pulmonary congestion or typical symptoms and signs of HF, aged over 18, and NYHA functional class II-IV

What does the study involve?
This study compares mortality and readmission in heart failure patients who participated in heart failure disease management programs (HFDMP group) and heart failure patients who received standard care (non-HFDMP group) over a 1-year follow-up period after discharge. The HFDMPs include a patient education program delivered by the lead nurse of the HFDMP; a cardiac rehabilitation program provided by a physical therapist; consultation with a dietician, and consultation and assessment by a psychologist. The patients are followed up for at least 1 year after discharge or until death. Patient characteristics and clinical demographic data are compared between the two groups.

What are the possible benefits and risks of participating?
Possible benefits include improved survival, reduced readmission, improved life quality and exercise capacity. There are no risks of participating.

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2013 to December 2016

Who is funding the study?
Chang Gung Medical Foundation (Taiwan)

Who is the main contact?
Dr Shyh-Ming Chen
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Impact of multi-disciplinary treatment strategy on systolic heart failure outcome

Study objectives
The multi-discipline disease management program is beneficial for heart failure patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2015, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Rd. Taipei, Taiwan, ROC 10507; Tel: +886 (0)3 3196200; Email: violet1202@cgmh.org.tw), IRB no.: 104-5591B

Study design
Longitudinal case-control study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure with reduced ejection fraction

Interventions
This observational cohort study compared mortality and readmission in heart failure patients who participated in a heart failure disease management programs (HFDMP group) and heart failure patients who received standard care (non-HFDMP group) over a 1-year follow-up period after discharge (December 2014 retrospectively registered). The components of the intervention program included a patient education program delivered by the lead nurse of the HFDMP; a cardiac rehabilitation program provided by a physical therapist; consultation with a dietician, and consultation and assessment by a psychologist. The patients were followed up for at least 1 year after discharge or until death. Patient characteristics and clinical demographic data were compared between the two groups. Cox proportional hazards regression analysis was performed to calculate hazard ratios (HRs) for death or recurrent events of hospitalization in the HFDMP group in comparison with the non-HFDMP group while controlling for covariates.

Intervention Type
Other

Primary outcome(s)
Recurrent events of hospitalization assessed using medical records and telephone contact at one year

Key secondary outcome(s))
Total mortality assessed using medical records and telephone contact at one year

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. HF patients admitted to hospital with reduced EF (EF<40%)
2. Radiographic evidence of pulmonary congestion or typical symptoms and signs of HF
3. Age > 18 years
4. NYHA functional class II-IV

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Severe respiratory failure under ventilator support
2. Dementia
3. Expectation of short survival
4. Discharge to a geriatric clinic or home care
5. Current follow-up treatment at the nurse-led HF clinic

Date of first enrolment
01/07/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
123 Ta Pei Rd., Niao Sung Dist.
Kaohsiung City
Taiwan
83301

Sponsor information

Organisation
Chang Gung Medical Foundation

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Shyh-Ming Chen (syming99@gmail.com) and Yu-Tung Huang (anton.huang@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2019	09/06/2020	Yes	No