

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

Submission date 24/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/06/2020	Condition category Circulatory System	<input type="checkbox"/> 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

Contact name
Dr Shyh Ming Chen

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

Recurrent events of hospitalization assessed using medical records and telephone contact at one year

Secondary outcome measures

Total mortality assessed using medical records and telephone contact at one year

Overall study start date

01/01/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

159

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

Sponsor details

123 Ta Pei Rd., Niao Sung Dist.
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syming99@cgmh.org.tw

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Planned publication in BMC Cardiovascular Disorders

Intention to publish date

01/10/2019

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