ISRCTN35096435 https://doi.org/10.1186/ISRCTN35096435

Randomised clinical trial to assess the efficacy of a multifactorial intervention in order to reduce hospitalisation and improve quality of life in patients with heart failure

Submission date
03/11/2004

Recruitment status
No longer recruiting

Registration date
01/02/2005

Overall study status
Completed

Last Edited
23/07/2009

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
IC-DOM

Study objectives
To assess the efficacy of a multidisciplinary non-pharmacologic intervention to reduce mortality and rehospitalisation, and to improve quality of life in patients with heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Heart Failure

Interventions
A multidisciplinary approach to patient education and counselling, optimisation of the treatments (drugs, diet, exercise), monitorisation of the electrolyte concentrations if necessary, and teaching education on self monitoring and management. The number of scheduled home visits will be 12 (every month), with telephone calls every 15 days.

Control:
Patients in the control group will be assigned to conventional care receiving standard treatments.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The combination of cardiovascular mortality and rehospitalisations (emergency room and/or hospital) at one year.

Key secondary outcome(s))

1. Total mortality or rehospitalisation for any reason
2. Rehospitalisation due to heart failure
3. Time until rehospitalisation
4. Days of hospitalisation
5. Quality of life related to health

Statistical models to be used will be survival analysis and Cox regression.

Completion date
30/09/2006

Eligibility

Key inclusion criteria
400 patients recruited from four hospitals in Catalonia: Vall dHebron Hospital, Clínic Hospital, Dos de Maig Hospital and Vic Hospital.

Inclusion Criteria:
Males and females without any limit of age, discharged from the hospital with the diagnosis of heart failure following the criteria of the European Society of Cardiology.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with heart failure due to reversible causes (hyperthyroidism, tachyarrhythmia, valve disease candidate for surgery)
2. Patients with concomitant chronic disease (cancer, chronic renal failure etc.)
3. Patients with poor mental function or any other reason to expect that the patient may have difficulty in complying with the requirements of the study

Date of first enrolment
01/01/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Spain

Study participating centre
Sardenya Primary Care Center
Barcelona
Spain
08025

Sponsor information

Organisation
Sardenya Primary Care Center (Spain) - in collaboration with the Catalan Foundation Institute of Pharmacology

Funder(s)

Funder type
Government

Funder Name
Catalan Department of Health (Agencia d'Avaluacio de Tecnologia i Recerca Mèdiques) (Spain)

Funder Name
Educational grants from:

Funder Name
1. Pfizer (Spain)

Funder Name
2. Almirall-Prodesfarma SA (Spain)

Funder Name
3. Sanofi-Synthelabo (Spain)

Funder Name
4. AstraZeneca (Spain)

Funder Name
5. Novartis (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2009		Yes	No
Protocol article	protocol	30/09/2005		Yes	No