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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet

### 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 measure
The combination of cardiovascular mortality and rehospitalisations (emergency room and/or hospital) at one year.

### Secondary outcome measures
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.

### Overall study start date
01/01/2004

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
400

### 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
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## Sponsor information

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

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### Sponsor type
Hospital/treatment centre

## 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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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? |
|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Protocol article | protocol | 30/09/2005 | Yes | No |
| Results article | results | 01/04/2009 | Yes | No |