

# Evaluation of a strategy to diminish admissions in patients with heart failure

<b>Submission date</b> 21/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/10/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**  
EBM-012008

# Study information

## Scientific Title

Evaluation of a strategy to diminish admissions in patients with heart failure: a randomised controlled open clinical trial

## Acronym

Tele-EMAI

## Study objectives

Patients with heart failure may benefit from at home telemonitorisation of their condition plus multifaceted personalised intervention compared with multifaceted personalised intervention alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Local Medical Ethics Board (CEIC Gipuzkoa) approved on the 23rd January 2008 (ref: Acta 01/08)

## Study design

Randomised controlled open clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Heart failure

## Interventions

Control group:

Automated program for opportunity/appropriateness of drug treatment with a personalised and monitored physical activity (aerobic) program. Follow-up telephone calls will take place on day 3 and 6, and every 15 days thereafter by the appointed nurse, and a telephone line and email address will be accessible 24 hours a day.

**Intervention group:**

As above, plus at home measurement twice daily of transdermal oxygen saturation, temperature, weight, blood pressure, cardiac and respiratory frequency, and in some cases, electrocardiogram (ECG). These measurements are sent by GSM to the hospital team.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Measured at the end of the study (see above anticipated end date):

1. Number of admissions
2. Number of emergency department visits

**Secondary outcome measures**

Measured at the end of the study (see above anticipated end date):

1. Quality of life (36-item short form health survey [SF-36]) at the beginning and end of the study
2. Perceived quality of medical attention, measured using the Spanish SERVQHOS questionnaire, at the beginning and end of the study

**Overall study start date**

20/02/2008

**Completion date**

31/12/2009

## **Eligibility**

**Key inclusion criteria**

1. Patients of any gender, aged older than 65 years
2. Heart failure stage III - IV New York Heart Association (NYHA)
3. At least two admissions during the previous year

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

70 patients

**Key exclusion criteria**

1. Moderate or severe dementia
2. Physical disability for aerobic activities
3. Refusal to participate

**Date of first enrolment**

20/02/2008

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Clinical Epidemiology Unit

San Sebastian

Spain

20014

## Sponsor information

**Organisation**

Hospital Donostia (Spain)

**Sponsor details**

c/o Jose I Emparanza

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hospitaldonostia.org/index2.htm>

**ROR**

<https://ror.org/04fwzm96>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hospital Donostia (Spain)

### **Funder Name**

Saludnova S.Coop (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