

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

Submission date 21/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/10/2009	Condition category 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

ROR

<https://ror.org/04fkwzm96>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Donostia (Spain)

Funder Name

Saludnova S.Coop (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration