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Telemonitoring in heart failure

Submission date 14/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/02/2010	**Overall study status** Completed	
Last Edited 27/06/2012	**Condition category** Circulatory System	

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
Telemonitoring in heart failure: a multicentre randomised trial

Study objectives
A heart failure clinic using telemonitoring of weight, blood pressure, heart rate and an automatic symptoms questionnaire allows to reduce the hospitalisation frequency, its duration and mortality. It also increases quality of life and reduces the number of unplanned consultations with the first and second line.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of Jessa Hospital approved on the 29th November 2007 (ref: 07.70 /cardio07.13)

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Congestive heart failure

Interventions
Telemonitoring will consist of daily patient self-measurements of body weight, blood pressure and heart rate with devices that allow automatic transfer of registered data to a web-site. This web-site will trigger E-mail alerts to care providers if data are out of limits, or if data have not been received. The tele-monitoring approach will be assisted by a central call centre, allowed to contact patients if technical problems with devices are suspected. The patients will also be called by an automatic telephone system to answer a short symptom questionnaire once every week.

The total follow-up in control patients, and intervention for other patients, is 6 months.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Number and duration of hospitalisation after the start of the study
2. Number of unplanned consultations with the heart failure team and GP
3. Number of phone calls (and amount of time spent) between the HF nurse and the patient
4. Quality of life (Minnesota Living with Heart Failure Questionnaire)
5. Mortality rate
6. Number of medication changes
7. Number of changes in alert limits

Measured at entry of study, and after 6 months of follow-up.

Secondary outcome measures
Blood B-type natriuretic peptide (BNP) content, measured at entry of study, and after 6 months of follow-up.

Overall study start date
01/04/2008

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Patients hospitalised for decompensated heart failure, necessitating intravenous (IV) diuretics or augmentation of oral (PO) diuretic, IV inotropic or IV vasodilator. Patients should be stabilised with treatment including angiotensin converting enzyme (ACE) inhibitors (or angiotensin II receptor antagonists [AIIA]), betablockers and diuretics at discharge.
2. Patients should be capable of understanding the aims of the study and to use the telemonitoring system
3. Aged between 50 and 85 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Reversible forms of heart failure
2. Heart failure due to aortic stenosis
3. Isolated right heart failure

4. Patients residing in "elderly homes"
5. Severe renal disease (glomerular filtration rate [GFR] less than 20 ml/min), planned dialysis in the next 6 months
6. Planned implantation of biventricular pacemaker, or cardiac surgery
7. Life expectancy less than 1 year
8. Severe pulmonary disease

Date of first enrolment
01/04/2008

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Jessa Hospital
Hasselt
Belgium
3500

Sponsor information

Organisation
Heart Centre Hasselt vzw (Belgium)

Sponsor details
Begeveldstraat
Bilzen
Belgium
3740

Sponsor type
Hospital/treatment centre

Website
http://www.jessazh.be/

ROR
https://ror.org/03tw90478

Funder(s)

Funder type
Research organisation

Funder Name
Heart Centre Hasselt vzw (Belgium)

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?
Results article	results	01/03/2012		Yes	No