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Better Efficacy in Lowering events by General practitioner's Intervention Using remote Monitoring in Heart Failure

Submission date 30/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/01/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/01/2008	**Condition category** Circulatory System	[_] Individual participant data [_] 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
N/A

Study information

Scientific Title

Acronym
BELGIUM-HF Registry & Trial

Study objectives
To test the hypothesis that general practitioner's intervention triggered by an alarm generated by an algorithm based on non-invasive vital sign home telemonitoring measurements in moderate to severe heart failure patients may reduce the rate of hospitalisations for heart failure, mortality or both.

The BELGIUM-HF Registry and Trial is a study that will be conducted in two steps.
The primary objective of the registry is to identify predictors of death, heart failure recurrence requiring hospitalisation, or both, and to validate simple and robust interventional algorithms based on weight, blood pressure and pulse transmitted by a telemonitoring system and to test those algorithms in subgroups of patients.

The primary objective of the subsequent randomised trial is to demonstrate a reduction in the incidence of Heart Failure (HF)-related hospitalisations or all-cause mortality in HF subjects managed with the the telemonitoring/interventional algorithm strategy as compared with HF subjects managed with the telemonitoring/usual care strategy over a period of 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Trials at the Saint-Jean Clinic (Commission d'éthique Expérimentation Humaine de la Clinique Saint-Jean), Brussels. Date of approval: 10/10/2007 (ref: 2007-284)

Study design
Parallel-group, prospective, single-centre, phase III, randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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

Systolic heart failure

Interventions
BELGIUM-HF Registry: No intervention. Duration of the Registry: 6 months. Follow-up visits will take place at 3 and 6 months.

BELGIUM-HF Trial: General practitioner's intervention based on an alarm generated by a predefined algorithm applied to the telemonitoring system and based on daily measured blood pressure, pulse and weight versus usual care (control). Types of intervention: none, medication changes, cardiologist referral, out-patient clinic referral, emergency room referral, hospitalisation.

Duration of intervention: 6 months

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Primary outcome measures in the Randomised Trial:
1. Incidence of HF-related hospitalisations (Duration of follow-up: 6 months)
2. All-cause mortality (Duration of follow-up: 6 months)

Secondary outcome measures
The following secondary end-points in the Randomised Trial will be assessed at 3 and 6 months except the cost-effectiveness evaluation, which will be carried out after the trial:
1. To demonstrate a reduction in the combined end-point of cardiac death, HF-related hospitalisations and cardiac-related urgent visits and interventions whichever comes first in HF subjects managed with the TeleMonitoring (TM) strategy compared to the Usual Care (UC) strategy
2. To demonstrate a reduction in HF-related hospitalisations in the TM arm compared to the UC arm
3. To demonstrate a reduction in all-cause mortality in the TM arm compared to the UC arm
4. To demonstrate a reduction in cardiac mortality in the TM arm compared to the UC arm
5. To demonstrate a reduction in the number of days spent at the hospital for HF-related conditions in the TM arm compared to the UC arm
6. To determine whether TM intervention improves functional status as assessed by a 6-minute walk test
7. To demonstrate an improvement in quality of life as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ) in the TM arm compared to the UC arm
8. To report a shift from "in-patient" to "out-patient" healthcare utilisation in the TM arm compared to the UC arm
9. To conduct a cost-benefit comparison between the two strategies

Overall study start date
15/12/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
BELGIUM-HF will be conducted in two steps: a prospective registry and a subsequent randomised trial. The BELGIUM-HF Registry will be completed before the BELGIUM-HF Randomised Trial starts. Patients who have been included in the Registry are eligible for the subsequent randomised trial if they meet the inclusion criteria at that time and have signed an informed consent regarding the randomised trial.

Inclusion criteria for both BELGIUM-HF Registry and Randomised Trial:
1. Subject with left ventricular systolic dysfunction, defined as a left ventricular ejection fraction < or = 40%, documented by echocardiography, contrast ventriculography or radionuclide angioscintigraphy within 6 months prior to inclusion
2. Subject has been hospitalised within the past 6 months for mild to severe heart failure defined as New York Heart Association (NYHA) class II to IV
3. Subject has received loop diuretics within 2 weeks prior to inclusion
4. Subject is at least 18 years of age
5. Subject or subject's legally representative has signed and dated the study informed consent

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Both

Target number of participants
Registry: 200 patients; Randomised trial: 500 patients

Key exclusion criteria
1. Subject who is scheduled for corrective valve surgery or coronary revascularisation, i.e. Coronary Artery Bypass Grafting (CABG) or Percutaneous Coronary Intervention (PCI) in a near future
2. Subject who has significant concurrent illness or condition not related to heart failure (i.e. terminal malignancy), associated with a life expectancy that is anticipated to be shorter than the expected duration of the trial
3. Subject on chronic renal dialysis
4. Pregnancy
5. Subject who has a health condition or psychic condition associated with poor compliance, including active alcoholism, mental illness or drug dependence
6. Subject directly involved in the execution of this protocol

Date of first enrolment
15/12/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Boulevard du Jardin Botanique 32
Brussels
Belgium
1000

Sponsor information

Organisation
Saint-Jean Clinic, Department of Cardiology (Belgium)

Sponsor details
Boulevard du Jardin Botanique 32
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01dd1x730

Funder(s)

Funder type
Government

Funder Name
Institute for the Encouragement of Scientific Research and Innovation of Brussels (Public funding) (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