

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

<b>Submission date</b> 30/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/01/2008	<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**  
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  $\leq 40\%$ , 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