HF Outpatient Monitoring Evaluation (HOME) Study

Published: 17-10-2011
Last updated: 27-04-2024

To determine if HF subjects whose treatment is assisted by a daily BNP measurement that is integrated into a home health management system will have improved clinical outcomes versus subjects whose treatment includes home health management but is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON38287

Source
ToetsingOnline

Brief title
HOME

Condition

- Heart failures

Synonym
Heart Failure; decompensatio cordis

Research involving
Human

Sponsors and support

Primary sponsor: Alere technologies
Source(s) of monetary or material Support: Alere San Diego

Intervention

Keyword: BNP, Cardiology, device, Heart Failure

Outcome measures

Primary outcome

The primary endpoint is the average number of *hard* events per subject with hard events defined as any of the following occurring over 180 days:

i. HF related death

ii. HF related readmissions to the hospital

iii. IV treatment with diuretics or unusual oral diuretic change in ER

iv. Unplanned outpatient treatments for decompensated HF

Secondary outcome

1) To determine the optimal frequency of home BNP testing and the changes in BNP concentrations that correlate with clinical HF decompensation and related adverse events in at-risk HF patients, during the early post-discharge time period in which patients are vulnerable to adverse events. This will be accomplished by analysis of patterns in daily BNP measurements observed in patients in whom HF decompensation occurs and in those in whom it doesn*t.

2) To determine the feasibility of frequent home BNP self-testing with the Test System in this population. This will be accomplished by completion of questionnaire by patients, patient feedback, and investigator experience.

Study description

Background summary

This is a multi-center, multi-national, three-arm, randomized, prospective Bayesian adaptive design clinical study to investigate whether intensive home monitoring with BNP, weight, and sign/symptoms will improve the outpatient management following treatment for heart failure (HF) decompensation.
Systolic dysfunction HF patients with low ejection fraction and elevated BNP levels admitted to hospital or treated as outpatient for decompensated HF were selected for this study, as this population is at high risk for recurrent decompensation / readmission and are most likely to benefit from enhanced home monitoring of their HF status
Daily fingerstick BNP levels will be obtained in this study so that frequent data points are available for analysis of trends and variability. However, these results will remain blinded to the subjects in all study arms and to their care providers in the daily health management and control arms of the study; the treating physicians and staff will see the BNP results only for the subjects in the daily BNP arm of the study and will use them to aid in therapy decisions.
Day 180 was selected as the duration of the core study period utilizing home BNP measurements, as there is a high rate of HF decompensation and readmissions during this time period. This time period is likely sufficient to differentiate normal biological variation in BNP from changes due to impending decompensation. It also was deemed to be a reasonable study duration from the perspective of likely patient compliance.
Follow-up telephone calls to subjects at 3 and 6 months after completion of home testing (Day 270 and Day 360 follow-ups) will be conducted to record any events as defined in the secondary composite end point in order to determine the possible long-term benefit of home health management with daily BNP testing.

Study objective

To determine if HF subjects whose treatment is assisted by a daily BNP measurement that is integrated into a home health management system will have improved clinical outcomes versus subjects whose treatment includes home health management but is blinded to BNP and to subjects whose treatment is blinded to both BNP and home health management results.

Study design

Multi-center, multi-national, three-arm, randomized, prospective Bayesian adaptive design
Daily BNP arm, daily health management arm and control arm

Subjects in the daily BNP arm will provide daily information from home regarding weight, signs and symptoms, and perform BNP self testing using the

Test system. All information will be automatically uploaded via wireless transmission to the Sponsor*s web based database where the results will be viewed by the treating Principal Investigator (PI) and staff. The results, including the daily BNP values, will be used by the PI/staff as an aid to treatment decisions and therapy adjustments for the subjects. The BNP result will be blinded to the subject.

Subjects in the daily health management arm will provide the same daily information regarding weight, signs and symptoms, and will also perform daily BNP self testing using the Test system except that the BNP results will be blinded to both the subject and the treating PI/staff. The treating PI/staff will be able to access the information from the web based database and use it as appropriate for treatment decisions.

Subjects in the control arm will be provided standard care as per the sites normal practice. During the observation period of the study, these subjects will also perform the daily testing routine (including measuring weight, and signs/symptoms and measuring BNP). All of these data will be blinded to the PI/staff and the BNP result will be blinded to the subject.

Subjects will return to the clinic for study visits at Day 7 (* 2 days) for assessment of proficiency using the HeartCheck System, and on Day 30 (* 3 days), Day 90 (* 10 days) and Day 180 (* 15 days) for clinical assessment, determination of events and HeartCheck system proficiency.
Follow-up phone calls at the Day 270 (± 15 days) and Day 360 (± 15 days) for all subjects will be conducted for determination of events counted toward the primary endpoint for long-term outcomes.

A randomization scheme will be employed to achieve equal balance of subjects among the three study arms at each clinical site and among all sites combined.

Study burden and risks

The burden of participation in this research study for the patient will be the same for patients included in all three study arms and will consist of the daily BNP testing with the fingerstick, and the completion of the questions regarding patient health, signs and symptoms of heartfailure. This daily testing and the completion of the questionnaires will take approximately 0.5 hours each day. The total volume of blood that will be taken from the patient in the course of the 180 day testperiod will be approximately (0.012X 180) 2.16ml.
The only risks to the subjects in the control arm or the daily health management arm of
the study due to study participation are those related to performing the biomarker blood
sample collections, fingerstick blood sampling and use of the Test System. The

risks of
obtaining blood via venipuncture or fingerstick are minimal and may include pain,
bleeding, bruising, swelling or infection at the site of the puncture. The risks associated
with use of the Test System are negligible, as the device has been safety tested for
electrical discharge, electromagnetic radiation, etc per guidelines and procedures.
The risks to subjects in the daily BNP arm of the study, in addition to the risks described
above related to blood sample collection and use of the Test System, are listed as follows:
1. The self-test BNP values obtained by subjects using the Test System at home will
be used by their treating physician as an aid in therapy adjustments and in the management of their heart failure. The accuracy of self-test BNP results obtained
by heart failure patients has not been fully validated. There is some risk that inaccurate BNP values will be obtained by the subject and that these BNP values will influence the therapy adjustment decisions made by the treating investigator
in a way that may be hazardous to the patient. The risk of an inaccurate result is
considered low given that the Test System is fully validated to give accurate results when used by professional operators (has CE Mark for this use), was designed to be easy to use, and that subjects will be well-trained and undergo two
proficiency assessments before they are fully enrolled in the study. Moreover, the
treating investigators will be determine if the BNP levels are consistent with the
subject*s clinical signs and symptoms as well as their previous BNP levels as part
of an overall assessment. Therefore the risk of hazard to the patient, due primarily to over or under dosing of medications, as a result of erroneous BNP level obtained by the subject, is considered to be low.
2. The BNP values obtained by subjects at home will be transmitted by a wireless system to a web portal through which treating physicians can observe and act upon these results. The transmission and web-portal software of this system have been verified by thorough software testing and processes but have not been fully validated. There is a risk that a BNP value will be incorrectly transmitted and will influence the therapy adjustment decisions made by the treating investigator
in a way that may be hazardous to the patient. The risk of an inaccurate transmission is considered very low given the testing that has been done and because the system has been used in an observational study with no evidence for

erroneous transmission. Moreover, the treating investigators will be determine if
the BNP levels are consistent with the subject*s clinical signs and symptoms as well as their previous BNP levels as part of an overall assessment. Therefore the
risk of hazard to the patient, due primarily to over or under dosing of medications,
as a result of erroneous BNP value being transmitted is considered to be very low.

Contacts

Public
Alere technologies

Lower Bioreliance Building, Stirling University Innovations Park , Stirling
FK9 4NF
GB
Scientific
Alere technologies

Lower Bioreliance Building, Stirling University Innovations Park , Stirling
FK9 4NF
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a. Consenting Adults at least 18 years of age

b. Prior or concurrent diagnosis of HF with LVSD (LVEF<=40%);
c. Deemed suitable for participation in this study;
Note: Home Health Management and therapy guided by the results of home testing are not appropriate for every patient. All potential subjects should be evaluated and deemed suitable for participation in this home health management study on the bases of their anticipated ability to understand and perform the daily testing activities, the likelihood of compliance, and the expectation that guided therapy would have a benefit to the patient. Special attention should be given when evaluating patients who are >= 75 years of age. ;
d. Meets on of the criteria below:
i. Enrolled within 30 days of an ADHF event where at least one BNP value during the hospital admission or clinic visit was > 300 pg/mL (or NT-pro-BNP > 1500 pg/mL) and there is an intent to treat for heart failure;
OR
ii. Seen in an outpatient setting (i.e. heart failure clinic, general practice or cardiology office, urgent care unit) with a documented history of HF and with signs of worsening HF condition or decompensation, where worsening HF condition is defined as one or more of the following;
1. Increase in NYHA class with worsening symptoms (i.e. dyspnea, fatigue) at same level of activity
2. Symptoms requiring change in dosage of one or more of the following medications:
a. diuretic
b. beta blocker
c. ACE inhibitor
3. Physical evaluation consistent with worsening HF signs (i.e. elevated JVP, ankle edema, dyspnea, abdominal distension, >4 lb or >1.8 kg weight increase in past week)
4. HF admission in last 30 days with a documented BNP > 300 pg/mL (or NT-pro-BNP > 1500 pg/mL) during or since admission
AND
e. Successfully trained and deemed proficient on how to perform a fingerstick and to use the Test System. Each subject will undergo two proficiency assessments.
i. The first assessment will be performed at the time in which the subject is found to meet the inclusion criteria, and deemed willing, able and reliable to complete the study tasks, and following initial training on the use of the test system. Successful completion of this first proficiency assessment will result in the enrolment of the subject into the study.
ii. The second assessment will be performed following one week (7 days ± 2 days) of home testing to demonstrate retention of the training. Successful completion of this second proficiency assessment will result in randomization of the subject into one of the three study arms of the study. Failure to demonstrate proficiency at this second assessment will result in the withdrawal of the subject from the study.

Exclusion criteria

a. Unwilling or unable to provide written informed consent;
b. Acute coronary syndrome (ACS) that is a primary diagnosis; or secondary diagnosis that is concomitant with the primary diagnosis of decompensated HF and for which treatment will be provided.

Note: A history of ACS is not cause for exclusion if it is not concomitant with the present decompensated HF for which admission is being made. Small elevations in cardiac troponin that are considered by the treating physician to be associated with myocardial injury due to the acute decompensated HF and not due to a concomitant ACS or myocardial infarction are not a basis for exclusion.
c. Previous cardiac transplantation - or cardiac transplantation anticipated within 3 months;
d. Current or planned use of a left ventricular assist device (LVAD), use of outpatient intravenous inotropic HF therapy, major surgical procedure or percutaneous coronary intervention within 3 months;
e. Life expectancy less than 6 months due to causes other than HF or cardiovascular disease (e.g., cancer);
f. End stage renal disease (dialysis dependency);
g. Receiving any investigational medication;
h. Hematocrit outside the 25 to 50% range of the HeartCheck system;
i. Prisoner or other institutionalized or vulnerable individual;
j. Dementia, tremors or other impediments to performing daily home BNP testing via fingerstick (unless BNP testing will be conducted by qualified caregiver);
k. Deemed by the investigator not to be likely to comply with study-mandated procedures or instructions;
l. Residence in regions where either transmission of test system data or home visits are not possible.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	30

Type:	Anticipated

Medical products/devices used

Generic name:	In vitro Diagnostic Device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	17-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-04-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ClinicalTrials.gov

Register	ID
CCMO	NL34424.042.11