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Observational study to predict readmission for heart failure patients

Submission date
31/01/2013

Recruitment status
No longer recruiting

Registration date
18/04/2013

Overall study status
Completed

Last Edited
24/03/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure becomes more common as people get older. About 1 in 15 of people aged 75-84 and just over 1 in 7 people aged 85 and above have heart failure. Our study is designed to investigate the reasons why people with heart failure are frequently readmitted to hospital and why they sometimes have a lengthy stay. We expect that this research will lead to improvements in the future management of patients by identifying new ways to identify those patients with the highest risk of readmission and an increased length of stay in hospital.

Who can participate?
Patients who are admitted to hospital with either a diagnosis of heart failure or who are prescribed fluid overload reducing medicines (diuretics).

What does the study involve?
If you agree to take part in the study, you will be asked to undergo the following tests and procedures. They are all voluntary and you can withdraw or refuse any of the tests as you wish. Many are tests you would have as part of your normal care, including (approximate times):
A physical examination including measuring your height, weight, blood pressure, heart rate and blood oxygen levels using a plastic finger probe. We will also look at how comfortable you are lying flat. (20 Minutes)
A heart trace (ECG) which records the electrical activity of your heart using sticky patches (Electrodes). (5 Minutes)
A heart ultrasound scan (Echocardiogram, similar to the scan used during pregnancy to look at babies) to review the functioning of your heart. It is not painful but may cause slight discomfort to your chest due to the positioning of the probe. (20 Minutes)
The following are not part of routine care (approximate times):.
Questionnaires to assess your health in general and how your symptoms are affecting your everyday activities and sleep (this may take an hour of your time but you dont have to do it all in one go)
A breathing test (spirometry). We will ask you to blow into a plastic tube. (5 Minutes)
Blood (at most 45 ml or 9 teaspoons of which 4 teaspoon are for research purposes) and urine tests to review the status of your heart and general health. (10 Minutes)
A corridor walk test (up to 50 metres, but you will only be asked to do this if you are able to and

you can stop at any time). (10 minutes)
A hand grip strength test, if you are willing and able to do it. (2 Minutes)
A get up and go timed test which measures how long it takes you to get up out of chair. (5 minutes)
A bio-impedance test, this is a test similar to an ECG but uses a small electrical current (that you cannot feel) to measure the amount of excess fluid in your body. (5 minutes)
Please remember you can refuse any or all of these tests at any time.

What are possible benefits and risks of participating?
You will not receive any expenses or payments for participating in this study but knowledge resulting from this research may help in treatment of future heart failure patients. Blood tests can cause some pain and bruising. The walking test may cause chest pain (angina) or disturb heart rhythm and this may make you feel sick and you might fall. However, there is someone there to help you and these are important medal findings that may change your treatment. The echocardiogram may cause some chest discomfort.
Please note: this is an observational study and as such you will not receive any experimental medicines.

Where is the study run from?
This study will be conducted at Castle Hill Hospital Hull and Hull Royal Infirmary.

When is the study starting and how long is it expected to run for
This study started in November 2012 and will run until 31 October 2014 . During these periods we will invite suitable in-patients to participate in this research study.

Who is funding the study?
Funding has been provided by Philips Healthcare for 1 year in the first instance and continuation of the study into the second year is subject to further funding being obtained from Philips Healthcare.

Who is the main contact?
Professor John G. F. Cleland
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13651

Study information

Scientific Title
An observational study to assess & predict the in-patient course, risk of readmission and mortality for patients hospitalised for or with Heart Failure

Acronym
OPERA HF

Study objectives
Patients with heart failure are at high risk of re-admission to hospital for cardiovascular and non-cardiovascular reasons. Re-admissions are distressing for the patient and costly to the NHS.

This study aims to build a holistic risk-stratification model using data obtained from heart failure patients admitted for or with heart failure to the Hull & East Yorkshire Hospitals NHS Trust.

The study has two components: a) risk stratification with long term follow-up and b) daily inpatient monitoring.

Approximately 1000 patients with a primary or secondary diagnosis of heart failure will be enrolled to the risk-stratification component during their in-patient stay. From these patients, approximately 100 with a primary diagnosis of heart failure who are expected to have an admission lasting several days will be invited to enrol in a heart failure management programme with serial, non-invasive, monitoring of their condition.

All patients will then be followed up indefinitely in order to provide longitudinal data from which to develop risk-stratification models to determine the degree and nature of risk (i.e.: is the patient likely to be re-admitted with heart failure, pneumonia or blackouts and if so how high is this risk).

It is envisaged that the risk-stratification model will assist healthcare providers to treat patients better and predict those at high risk of early hospital re-admission and death and the likely causes(s). Such a tool could make a substantial difference to patient care and result in a cost saving to the NHS by facilitating management tailored to the individual patients needs. At present there is no such tool available in routine clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and the Humber - Sheffield, First MREC approval date 29/08/2012, ref: 12/YH/0344

Study design
Non-randomised observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Development of risk model, Identifying the Nature of Risk and Developing Prediction Models
1. To develop one or more multi-dimensional risk stratification models to identify patients with heart failure at high risk of early death or re-admission (and its likely reason) who are in need of more intensive support during and after hospitalization and to identify those at very low risk that might be safe for early discharge.
2. Establish causes of admission or re-admission of patients with heart failure to the East Yorkshire Hospitals

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of patients with an optimal length of stay; Timepoint(s): Discharge.

Secondary outcome measures
No secondary outcome measures

Overall study start date
27/09/2012

Completion date

31/12/2017

Eligibility

Key inclusion criteria
Inclusion Criteria for the Risk Stratification Component:
1. Age >18 years
2. In hospital
3. Usual residence is in the catchment region for Hull & East Yorkshire Hospitals Trust (this enables efficient follow-up)
4. Either
4.1. Treated with loop diuretics Or
4.2.Clinical diagnosis of heart failure
5. Willing and able to provide informed consent

Additional Inclusion Criteria for the Monitoring Component of the Study:
Heart failure as a dominant diagnosis meaning that
1. There is objective evidence of cardiac dysfunction as evidenced by a least ONE of the following:
1.1. Left ventricular ejection fraction <= 40%
1.2. Left atrial dimension >4.0 cm (or >2.5 cm/m in height)
1.3. NT ProBNP > 400pg/ml (>47.3pmol/L (or BNP >150 pg/ml) if in sinus rhythm or >1,200pg/ml (or BNP >450pg/ml) if in atrial fibrillation
2. The patient is receiving loop diuretics
3. Target Gender: Male & Female ; Lower Age Limit 80 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 1000

Total final enrolment
1145

Key exclusion criteria
Unable to understand and comply with protocol or to give informed consent. There are no other exclusion criteria for the risk stratification study.

Additional Exclusion Criteria for the Monitoring Component of the Study:
The duration of admission is likely to be determined by the need for treatment other than for

heart failure (for instance, patients with infective endocarditis, major stroke disability or major cognitive impairment will be excluded).

Date of first enrolment
27/09/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust

Sponsor details
Anlaby Road
Hull
England
United Kingdom
HU3 2JZ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Industry

Funder Name
Royal Philips Electronics NV

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	01/04/2018		Yes	No
Results article		01/03/2021	24/03/2021	Yes	No