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Feasibility study of the use of point-of-care NP measurement

Submission date
04/12/2017

Recruitment status
No longer recruiting

Registration date
07/12/2017

Overall study status
Completed

Last Edited
31/07/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart failure is a condition where the heart does not pump blood around the body as well as it should. Although it is called heart “failure”, the heart is still working, but it might need extra help to make sure it works as well as it can. When someone has been diagnosed with heart failure, they are regularly monitored by their health care team. A blood test for natriuretic peptide (NP) is sometimes used to help diagnose heart failure, and there is some research that shows that monitoring NP may also be useful for monitoring patients with heart failure. It is possible for a doctor or nurse to measure NP from a blood sample themselves with a special machine (a “point of care” test), instead of sending it to a laboratory. This means that they get the result quickly, which would be important if they want to use it to make a decision about whether to change someone’s treatment, or to send them to hospital. The aim of this study is to see if it is practical for a GP or nurse to use the quick blood test to monitor patients with heart failure during their normal care.

Who can participate?
Adults aged 18 and older who have a confirmed diagnoses of heart failure and are currently manged in a primary care setting.

What does the study involve?
Participants are asked to make three extra visits to their GP practice over a year to have the quick blood test, along with some laboratory blood tests and a general check of their heart health. It will be seen if it is practical for the quick blood test to be used when participants come to see a GP or nurse during that year about their heart failure. At the end of the study participants are asked and the GPs and nurses to take part in separate focus groups so that we can find out how they feel about the new test.

What are the possible benefits and risks of participating?
People who take part in the study will get extra monitoring during the study, including the new point of care test, but there is no guarantee that this will directly benefit them. However, all the results of the tests done during the study will be available to their GP, so that they can be used

to help care for them. The main risk of the study is the blood sample needed for the new test. This is a standard procedure, which may cause some pain and bruising, but should not result in any other problems.

Where is the study run from?
This study is being run by the Nuffield Department of Primary Care Health Sciences, University of Oxford (UK) and will take place in GP surgeries within the Thames Valley Primary Care Research Network (UK).

When is the study starting and how long is it expected to run for?
October 2016 to May 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Rafael Perera (Scientific)
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Contact information

Type(s)
Scientific

Contact name
Prof Rafael Perera

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

36644

Study information

Scientific Title
Feasibility study of the use of point-of-care NP measurement in primary care in patients with heart failure

Study objectives
The primary aim of the study is to determine the variability in natriuretic peptide measurements made using point-of-care technology in heart failure patients in primary care settings, including both between- and within- person variability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HSC REC B, 07/11/2017, ref: 234119

Study design
Non-randomised; Both; Design type: Process of Care, Device, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Primary care, Primary sub-specialty: Cardiovascular disease; UKCRC code/ Disease: Cardiovascular/ Other forms of heart disease

Interventions
This is a feasibility study. The intervention is point-of-care NT-proBNP measurement, using a Roche cobas h 232 device, added to current clinical measures at all visits. There is study visits at baseline, 6 and 12 months, as well as point-of-care measurement of NT-proBNP at routine visits for heart failure during the 12 month study period. Following the final study visit at 12 months, focus groups are held separately with patients and participating clinicians to discuss the acceptability of the intervention.practice or patient's home.

Intervention Type

Other

Primary outcome measure
Between- and within- person variability of point-of-care NP is measured using point-of-care NT-proBNP test results at baseline, 6 months, 12 months, and routine visits for heart failure.

Secondary outcome measures
1. Proportion of planned tests for which results are available is measured using the presence of expected point-of-care NT-proBNP tests results at baseline, 6 months, 12 months, and routine visits for heart failure
2. Proportion of NP tests that GPs report would have changed or did change decision-making process is measured using GP feedback on decision making at baseline, 6 months, 12 months, and routine visits for heart failure
3. Proportion of proposed tests actually carried out is measured using reports of point-of-care test use at baseline, 6 months, 12 months, and routine visits for heart failure
4. Patient acceptability is measured using 5 point Likert score at the 12 month visit
5. Clinician acceptability is measured using 5 point Likert score after the last patient visit at their site
6. Patient views about point-of-care NP testing in primary care is measured using a focus group after their 12 month visit
7. Clinician views about point-of-care NP testing in primary care is measured using a focus group after the last patient visit at their site
8. Recruitment rate is measured using a recruitment log at and before the baseline visit
9. Retention rate is measured using withdrawals before the 6 month and 12 month visits
10. Comparison to lab NT-proBNP measures is measured using point-of-care and lab NT-proBNP results taken at baseline, 6 months and 12 months
11. EQA comparison is measured using test samples at a convenient time for clinical staff
12. EQA precision assessment is measured using test samples at a convenient time for clinical staff

Overall study start date
01/10/2016

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Confirmed diagnosis of heart failure made by cardiologist and/or echocardiography
4. Currently managed in a primary care setting where the clinician is willing to take part in routine POC NP monitoring

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 27; UK Sample Size: 27

Total final enrolment
27

Key exclusion criteria
Participant is considered to be terminally ill or receiving palliative care for another condition only at the time of recruitment.

Date of first enrolment
21/02/2018

Date of final enrolment
20/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Primary Care Health Sciences
The University of Oxford
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials & Research Governance
Oxford
England

United Kingdom
OX1 2JD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Rafael Perera (rafael.perera@phc.ox.ac.uk). Following publication of the research, fully-anonymised data may be shared with other academic researchers, including those outside the UK, for research purposes only (e.g. for individual patient data meta-analysis). Data will be available for up to 10 years after conclusion of the research, and will be limited to quantitative data (i.e. excluding data from focus groups, for which consent to further sharing will not be available).

Consent and ethical approval for this form of sharing will be available, provided that data is not shared further by the recipient, and is used only for the agreed purpose.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.2	19/10/2017	07/12/2017	No	Yes
Protocol file	version V1.3	19/10/2017	07/12/2017	No	No
Basic results	version v1	28/07/2020	31/07/2020	No	No