

B-type natriuretic peptide (BNP) testing and monitoring in patients with heart failure (HF) in primary and secondary care in the UK

Submission date 09/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

B-type natriuretic peptide (BNP) is a substance in the blood that is raised in patients with heart failure. There is evidence that measuring BNP regularly over time and adjusting medications to lower BNP levels improves health outcomes in these patients. Currently, it is unknown whether any heart failure patients in the UK receive serial BNP monitoring and, if yes, whether this has changed patient management and improved clinical outcomes. The main aim of this study is to find out whether BNP testing and monitoring improves outcomes for patients with heart failure.

Who can participate?

Patients with heart failure aged 18 and over

What does the study involve?

Patient information is collated from GP practices and hospitals, and linked with hospital record data and death registry data. A small group of patients have BNP measurements recorded. Groups with and without BNP measurements are compared for differences in health outcomes. A health economic analysis is also undertaken to determine whether measuring BNP is cost effective in the NHS.

What are the possible benefits and risks of participating?

There will be no risk to patients because all information will be provided in a format that will not include names, addresses, date of birth, or any other identifiable information.

Where is the study run from?

University of Bristol (UK)

When is the study starting and how long is it expected to run for?

August 2013 to January 2015

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/102/03

Study information

Scientific Title
Effectiveness and cost-effectiveness of serum B-type natriuretic peptide (BNP or NT-BNP) testing and monitoring in patients with heart failure (HF) in primary and secondary care

Study objectives
Compared with symptom-guided therapy (standard care), BNP-guided testing and monitoring reduces mortality and hospital admission in patients with chronic heart failure in the UK and is cost effective to the NHS.

More details can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/1110203/#/>

Ethics approval required

Old ethics approval format

Ethics approval(s)

The cohort will be established by the UK Clinical Practice Research Datalink (CPRD), which holds standing ethical approval for observational studies using anonymised CPRD GOLD data. Our study therefore does not require separate ethical approval from an NHS Research Ethics Committee.

Study design

Longitudinal cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Heart failure

Interventions

Exposure: Any BNP measurement (single or multiple).

Comparator: No BNP measurement.

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Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

All-cause mortality within 12 months

Secondary outcome measures

1. Time from diagnosis of HF (time origin for all time-to-event analyses) to emergency in hospital admission/unscheduled readmission
2. Length of hospital stay
3. Prescribed medications on discharge
4. Time on medication
5. Time to change in medication
6. Annual rate of outpatient clinic and general practice attendance and associated investigations

Overall study start date

01/08/2013

Completion date

31/01/2015

Eligibility

Key inclusion criteria

All patients with primary diagnosis of heart failure in CPRD or NHFA, diagnosed between April 2005 and March 2013 (CPRD) and April 2009 and March 2013 (NHFA). HF diagnoses in CPRD will be identified using the Read codes. Code sets will be selected with the help of CPRD researchers and agreed by clinical members of the research team.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

All patients for whom linked data are available (estimated to be ~50,000).

Key exclusion criteria

Patients who do not meet the inclusion criteria above

Date of first enrolment

01/08/2013

Date of final enrolment

31/01/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Bristol

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04nm1cv11>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Protocol article	protocol	02/05/2014	22/01/2019	Yes	No
Results article	results	01/08/2017	22/01/2019	Yes	No
Results article	results	31/07/2018	22/01/2019	Yes	No
Results article	results of model-based cost-effectiveness analysis of B-type natriuretic peptide-guided care in patients with heart failure.	28/12/2016	22/01/2019	Yes	No
Results article	results of the healthcare costs of heart failure during the last five years of life.	01/12/2016	22/01/2019	Yes	No