

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

<b>Submission date</b> 09/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> 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?  
Dr Maria Pufulete  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Diagnostic

**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(s)**

All-cause mortality within 12 months

**Key secondary outcome(s))**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

University of Bristol

Bristol

United Kingdom

BS2 8HW

**Sponsor information****Organisation**

University Hospitals Bristol NHS Foundation Trust (UK)

ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2017	22/01/2019	Yes	No
<a href="#">Results article</a>	results	31/07/2018	22/01/2019	Yes	No
<a href="#">Results article</a>	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
<a href="#">Results article</a>	results of the healthcare costs of heart failure during the last five years of life.	01/12/2016	22/01/2019	Yes	No
<a href="#">Protocol article</a>	protocol	02/05/2014	22/01/2019	Yes	No
<a href="#">Participant information</a>	Participant information sheet	11/11	11/11	No	Yes

