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Identification of cardiac dysfunction in a GP outpatient setting using handheld echocardiography and brain natriuretic peptide (BNP) point of care testing

Submission date
21/09/2005

Recruitment status
No longer recruiting

Registration date
30/11/2005

Overall study status
Completed

Last Edited
06/08/2014

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with symptoms potentially indicative of heart failure usually present first to their general practitioner (GP). This study was designed to determine whether point-of-care testing of B-type natriuretic peptide (BNP) and/or handheld echocardiography (ECHO) improves the diagnostic ability of GPs in such patients (Screening Study) and whether baseline echocardiographic and biomarker measurements provide clinically relevant prognostic information (Prognostic Follow-Up Study). The feasibility of this program was tested in the preceding Training Study, which investigated whether expert training of limited duration and with standardized content and diagnostic directives enables GP to utilize BNP point-of-care-testing and ECHO in primary care. The study aims to clarify whether ECHO and/or point-of-care BNP testing improves the diagnostic and prognostic abilities of GPs in diagnostically naïve patients with suspected heart failure, and whether BNP and other biomarkers determined at baseline help to assess prognosis in this population.

Who can participate?
Patients aged over 18 in whom heart failure is suspected on clinical grounds, who present in a primary care setting in two different regions of Germany (North Rhine Westphalia and Bavaria).

What does the study involve?
The first part of the study (Training Study) aimed at the development of a stringent training program for the GPs regarding both performance and interpretation of ECHO and/or BNP testing and measured the time required to achieve a sufficient training level (correct diagnostic result in >80% of cases). The second part of the study (Screening Study) examines whether, and if yes, to what extent the diagnosis of heart failure in the primary care setting is improved by the use of the ECHO and/or BNP, while in the third part of the study (Prognostic Follow-Up Study) follow-up assessments of the patients are performed at 2.5 to 3 years and 5 to 6 years after trial enrolment in order to evaluate the long-term outcomes of the study population depending on different variables (echo parameters and biomarkers) measured at baseline.

GPs are randomly allocated to use one of the following four modalities for diagnosis of heart failure:
1. Assessment of clinical signs and symptoms only
2. Assessment of clinical signs and symptoms plus use of ECHO
3. Assessment of clinical signs and symptoms plus use of BNP testing
4. Assessment of clinical signs and symptoms plus ECHO plus BNP testing
Subsequently, all patients are referred to a cardiologist in private practice to provides the gold-standard diagnosis of heart failure within 2 weeks after the patients presentation to his GP. Subsequently, patients are followed up by questionnaires. All patients who participated in the first part of the study at study site Würzburg are invited to a comprehensive cardiological follow-up examination at the Comprehensive Heart Failure Centre of the Würzburg University Hospital.

What are the possible benefits and risks of participating?
There are no specific risks because the study involves standard routine diagnostic procedures to clarify suspected heart failure. A benefit may arise from the thorough diagnostic work-up patients undergo, since a first diagnosis or exclusion of heart failure is possible by the diagnostic procedures; further, alternative causes of the patients symptoms may be identified in the course of the examinations. All patients will receive from their GP optimized treatment of their condition according to current guidelines.

Where is the study run from?
The study is coordinated by Prof. Angermann at the Comprehensive Heart Failure Center (CHFC) at the University Hospital in Würzburg and by Prof. Erbel at the University Hospital in Essen. 12 cardiologists are involved and 48 general practitioners are involved in two different areas of Germany (Essen and Würzburg).

When is the study starting and how long is it expected to run for?
The study started in 2004 and continues with long-term follow ups until 2013.

Who is funding the study?
The study is funded by the Federal Ministry of Education and Research (Germany) as part of the Competence Network Heart Failure and is further supported by Philips Medical Systems and Biosite.

Who is the main contact?
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Study website
http://knhi.de/studies/tp-6a/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Diagnostic utility of point-of-care B-type natriuretic peptide and handheld echocardiography in the primary care assessment of patients with suspected heart failure the Handheld BNP Study, a four-arm randomised controlled trial

Acronym
Handheld BNP Study

Study objectives
Use of handheld echocardiography and/or BNP point-of-care testing improves the rate of correct heart failure diagnoses in a GP outpatient setting.

On 24/08/2009 the scientific title was added to this trial record.

On 04/08/2014 the following changes were made to the trial record:
1. The study design was changed from 'Four-arm diagnostic randomised controlled trial' to 'Four-arm diagnostic randomised controlled trial with a follow-up period of up to 5 years'
2. The anticipated end date was changed from 31/12/2006 to 01/11/2013

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the University of Wuerzburg and the State Ethics Committees of Bavaria and North Rhine Westfalia in 2004
Approval of Amendment 01: 25/07/2006
Approval of Amendment 02: 19/07/2010

Study design

Four-arm diagnostic randomised controlled trial with a follow-up period of up to 5 years

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Heart failure diagnosis

Interventions
This is a four-arm diagnostic cluster-randomised study. GPs are trained and certified by experts to handle the diagnostic tools; each GP diagnoses a predefined number of patients with suspected heart failure using:
1. No additional tools
2. Handheld echocardiography
3. BNP point of care test
4. Handheld echocardiography and BNP test

GPs are randomly allocated 1:1:1:1 to the four diagnostic modalities. Within 14 days the diagnosis of the GP is verified or falsified by a cardiologist.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Concordance/discordance of diagnosis between GP and cardiologist.

Secondary outcome measures
1. Agreement between BNP point of care test and BNP reference test at core lab
2. Time needed to train and certify GPs in the different diagnostic tools

Overall study start date
01/03/2004

Completion date
01/11/2013

Eligibility

Key inclusion criteria
1. Age >18 years
2. Written informed consent
3. A diagnosis of heart failure suspected by the GP solely on the grounds of history taking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
960

Key exclusion criteria
Diagnosis of heart failure confirmed or excluded earlier

Date of first enrolment
01/03/2004

Date of final enrolment
01/11/2013

Locations

Countries of recruitment
Germany

Study participating centre
Straubmühlweg 2a
Wuerzburg
Germany
97078

Sponsor information

Organisation

University of Wuerzburg (Germany)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00fbnyb24

Funder(s)

Funder type
Industry

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Funder Name
Philips Medizinsysteme Ultraschall (Germany)

Funder Name
Biosite Diagnostics GmbH (Germany)

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