Bayesian Hemodynamics model for personalized monitoring of congestive heart failure patients.
Translating physician*s reasoning into computational models.

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Development and clinical validation of a Bayesian network type model for heart failure, personalized for the individual patient, to monitor the status of heart failure.

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON47581

Source
ToetsingOnline

Brief title
Validation of a Bayesian Hemodynamics model for heart failure patiënts.

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Philips,Philips Research (Philips Group Innovation)

Intervention

Keyword: Bayesian, Heart failure, Hemodynamic

Outcome measures

Primary outcome

Laboratory outcomes:

* Na (mmol/l)

* K (mmol/L)

* eGFR (ml/min)

* serum creatinine (micromol/L)

* TSH (mu/L)

* GGT (IU/litre)

* AST (IU/litre)

* Pro BNP (ng/L)

* Lipid profile

* Hb (mmol/l)

12-lead ECG

* Heart rhythm

* Heart rate (BPM)

* QRS duration (ms)

* QRS morphology (LBBB/RBBB)

Transthoracic echocardiography

* Limitary protocol (Left Ventricular function and dimensions, Right

Ventricular function and dimensions, Mitral valve, Tricuspid valve, Inferior

Vena Cava dimensions)

X-thorax

Physical examination

* Weight (kg)

* Pulse pressure; systolic, diastolic, MAP (mmHg)

* Prominent neck veins

* Heart rhythm, manual (irregular, regular)

* Heart Sound (S3 Gallop)

* Heart murmurs: (valve insufficiency)

* Heart enlarged (apex

* SpO2 (%)

* Orthopnoea

* Dyspnoea

* Respiration rate (breaths/min)

* Pleura fluid

* Liver tender enlargement

* Nausea

* Pitting Edema (pretibial, bilateral)

* Pitting Edema (sacral when rising in the morning)

* Nocturia

Questionnaire

* *Did your weight increase last 24h, and how much? (yes/no)

* *Do you have more dyspnoea complains? (yes/no, if yes: 0-10 scale)

* *Have you noticed edema? (yes/no, if yes: 0-10 scale)

* *Do you feel fatigue? (yes/no, if yes: 0-10 scale)

* *Do you feel nauseous? (yes/no, if yes: 0-10 scale)

* *Have you contacted the hospital or your GP?* (yes/no)

Medication use

* Diuretics (kind, dosage)

* Inotropics (kind, dosage)

Secondary outcome

not applicable

Study description

Background summary

Heart failure (HF) is a serious and challenging syndrome. Globally 26 million people are living with this chronic disease and the prevalence is still increasing. Besides this growing number in prevalence, HF is also responsible for almost 1 million hospitalizations a year in the US and in Europe. Consequently, this has a major economic impact especially due to recurrent admissions of these patients. When we*re in the position to predict accurately if a patient is decompensating or not, we could prevent (un)necessary admissions as a result of heart failure. Philips® is developing a Bayesian Hemodynamics model for general practitioners. This model uses different observables, which can be measured at home. The outcome of the model could be

used as an aid in clinical decision making in HF patients.

Study objective

Development and clinical validation of a Bayesian network type model for heart failure, personalized for the individual patient, to monitor the status of heart failure.

Study design

The design is a prospective cohort study.
Data of 20 hospitalized HF patients will be collected, after initiation of HF treatment in the hospital. All observables will be collected every day during admission.
The results of the model (interpretation of the patient data) will be compared with one or two independent physicians interpretations of the lab values with respect to the probability/seriousness of heart failure.
No differences in treatment of the patients will be made due this project.

Study burden and risks

During admission, this study will be no additional risk for the patient and will not influence the treatment of the patient.
The additional burden will be minimal. It depends on the time of admission how much additional thoracic echocardiography's will be made, to the utmost an echocardiography will be made two times a week and once during dismiss. It takes 20-30 minutes to perform an echocardiography. The daily questionnaire will take 5 minutes and is partly similar to the daily anamnesis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be included in this study, the subject is admitted to the department of cardiology in the LUMC due to congestive heart failure.

Exclusion criteria

A subject will be excluded from the study if he or she does not meet the inclusion criteria. Thus when the patient isn't admitted to the department of cardiology due to congestive heart failure.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-10-2018
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	06-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL61810.058.17