

# PRognostic hEModynamlc profiling in the acUte ill eMergency department patient: PREMIUM registry

Published: 18-02-2011

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38388

### Source

ToetsingOnline

### Brief title

PREMIUM registry

### Condition

- Heart failures
- Infections - pathogen unspecified
- Central nervous system vascular disorders

### Synonym

; Acute CHF, Acute Stroke Syndrome; Acute Systemic Infection

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** bedrijf BmEye

## Intervention

**Keyword:** Emergency department, Hemodynamic, Nexfin

## Outcome measures

### Primary outcome

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### Secondary outcome

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## Study description

### Background summary

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### Study objective

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### Study design

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### Study burden and risks

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## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelenlaan 1117  
1081 HV Amsterdam  
NL

### Scientific

Vrije Universiteit Medisch Centrum

De Boelenlaan 1117  
1081 HV Amsterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

General:

18 years of age or older

Able to provide informed consent

No initiated therapy since arrival to the ED

Must be enrolled within 2 hours of arrival to the ED

Acute CHF

Recurrent or worsening (within 3 days) shortness of breath as the primary presenting ED complaint

Initial treating ED physician impression that the worsening dyspnea is most likely caused by decompensated CHF

Known history of physician diagnosed CHF

BNP level will be ordered by the treating physician as part of the patient's work up

Acute stroke syndrome:

Onset of abnormal neurological symptoms consistent with possible stroke, within the prior 24 hours, as the primary ED complaint

Initial treating ED physician impression that the abnormal neurological symptoms/signs are most likely caused by an acute stroke syndrome

Non contrast head CT will be ordered by the treating physician as part of the patient's work up

Acute Systemic Infection:

Any combinations of acute (within 3 days) symptoms and signs that the treating ED physician, after initial history and physical examination, attributes to a systemic infection

Blood cultures and/or a blood lactate will be ordered by the treating physician as part of the patient's work up

## Exclusion criteria

ESRD requiring hemo or peritoneal dialysis  
Suspected pregnancy  
Not able to be followed up in 30 days  
Patients with \*comfort only\* DNR status  
Patients with known STEMI  
Excessive agitation  
Transferred from another treating facility  
Known aortic valve disease, aortic insufficiency or aortic stenosis  
On continuous IV home infusions (such as milrinone, primacor)  
Known Left Ventricular Assist device (LVAD)  
Known prior enrollment in this study  
In current therapeutic Investigational study

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 27-04-2011

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Date:	18-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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	NL33780.029.10