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

Published: 18-02-2011
Last updated: 16-11-2024

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Ethical review	Approved WMO
Status	Completed
Health condition type	Heart failures
Study type	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

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Scientific

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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