Improve Management of heart failure with Procalcitonin - Biomarkers in Cardiology 18 (Short title: IMPACT-EU)

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Adding PCT measurements to standard diagnostics to support decision making regarding initiation of antibiotics. To evaluate an advantage of PCT guided prescription of antibiotic treatment over established treatment practice with respect to 90-day…

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

Summary

ID

NL-OMON42767

Source
ToetsingOnline

Brief title
IMPACT-EU

Condition

- Heart failures

Synonym
bacterial infection, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Thermo Fisher Scientific BRAHMS GmbH
Source(s) of monetary or material Support: Thermo Fisher Scientific BRAHMS GmbH

Intervention

Keyword: antibiotic guidance, heart failure, infection, Procalcitonin

Outcome measures

Primary outcome

90-day all-cause mortality of patients (# of days from randomization)

Secondary outcome

a) 30-day all-cause mortality

b) Hospital all-cause readmission within 30 days

c) Number of patients with diagnosis of pneumonia during index hospitalization

Study description

Background summary

To evaluate an advantage of PCT guided prescription of antibiotic treatment over established treatment practice with respect to 90-day all cause mortality in Europe.

Study objective

Adding PCT measurements to standard diagnostics to support decision making regarding initiation of antibiotics. To evaluate an advantage of PCT guided prescription of antibiotic treatment over established treatment practice with respect to 90-day all cause
mortality in Europe.

Study design

Prospective, multicentre, randomized-controlled, interventional biomarker study

Study burden and risks

Control group: no additional risks
PCT-group. Through false high or false low PCT values a wrong decision could be made about the antibiotic therapy.

Patient with PCT above cutoff: in this group the prescription of antibiotics is expected to be higher than the standard of care. Therefore more patients could suffer from side effects of antibiotics.
Patients with PCT below the cutoff: In this group is expected that less antibiotics are prescribed than according to standard of care. In previous studies it was shown that the antibiotic treatment can be reduced through PCT without worsening of clinical condition. However it cannot be excluded that the treatment according to PCT could have a negative effect.

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

1. Patients who present to the ED with leading symptom dyspnea
2. Suspected or known heart failure

3. MR-proANP>300 pmol/L, BNP>350 ng/ml or NT-proBNP>1800 ng/l
4. Patient has given written Informed Consent within study timelines to allow antibiotic treatment within 8 hours
5. Adult patients (i.e. >18 years of age)
6. Hospitalization for at least 1 overnight stay planned

Exclusion criteria

1. Patient participates in any other interventional clinical trial
2. Trauma related shortness of breath
3. Patient diagnosed with lung or thyroid cancer
4. Known terminal disease with life expectancy of less than 6 months, e.g. advanced metastasized cancer disease
5. Organ transplant requiring immunosuppression
6. Abdominal, vascular or thorax surgery within the last 30 days
7. End stage/advanced HF * defined by planned heart transplantation, or cardiogenic shock
8. Female patients who have given birth within 3 months before study enrolment
9. Current use of antibiotics or requirement of immediate antibiotic therapy before randomization and measurement of PCT
10. End stage renal failure requiring dialysis
11. Patient is not willing, or it is not possible or advisable for the patient, to follow the study schedule, including antibiotic therapy and 90 days follow up
12. Patient has already participated in the clinical trial previously
13. Pregnant or lactating women
14. Patients who are institutionalized by official or judicial order
15. Dependants of the sponsor, the CRO, the study site or the investigator

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	17-12-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	BRAHMS PCT sensitive Kryptor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT02392689
CCMO	NL54246.042.15