Higher accuracy and cost-effectiveness using a novel biomarker for Treatment of Emergency Medicine Patients with fever

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25141

Source
Nationaal Trial Register

Brief title
HiTEMP

Health condition

Procalcitonin, emergency department, bacterial infection, antibiotics, antibiotic stewardship

Procalcitonine, spoedeisende hulp afdeling, bacteriele infectie, antibiotica

Sponsors and support

Primary sponsor: Erasmus University Medical Center (Erasmus MC) Rotterdam
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

•Number of febrile patients who are prescribed antibiotics in the ED

•Safety of PCT-guided therapy, defined as 30 days mortality, Intensive Care Unit (ICU) admittance, or a return visit to the ED within 14 days.
• Accuracy of PCT and CRP as area under curve (AUC) compared with diagnosis of bacterial or viral infection by culture, polymerase chain reaction (PCR) and serology

Secondary outcome

•Hospital treatment costs (Costs of PCT testing (treatment group only), antibiotics, and other related medical consumption during admittance).

•Related medical consumption during follow-up. (General practitioner (GP) and additional hospital visits, diagnostics and medication)

•Days absence from work and reduced productivity while at work. (if applicable)

•Costs of hospital stay (hospitalized patients) or ICU stay (critically ill patients).

•Costs of extramural antimicrobial therapy.

Study description

Background summary

The implementation of PCT testing could help in achieving early diagnosis and adequate management of febrile patients with infectious diseases in the emergency department.

Study objective

PCT is a biomarker that can detect bacterial infections more specific compared to current biomarkers and will result in more accurate antibiotic therapy. Consequently, in cases with other infections (e.g. viral) it will avoid unnecessary antibiotic therapy. Effective antibiotic use will lead to a reduction of antibiotics resistance and costs.

Primary:
- To investigate efficacy of PCT-guided antibiotic therapy in the ED
- To evaluate the safety of PCT-guided antibiotic therapy in the ED

Secondary:
- To study if PCT-guided therapy is cost-effective
- To investigate the accuracy of PCT as biomarker for bacterial infection

Study design

Inclusion will be two years

Intervention

For the primary objective ‘efficacy’ the study is set up a superiority study, in which the new intervention is compared to the current standard-of-care.
For the primary objective ‘safety’ the study is set up as a noninferiority study to investigate whether the new intervention (PCT-guided therapy) is at least as safe as the established intervention.

Intervention: Patients will be allocated into two groups:

1. A control group (standard-of-care)
2. Intervention group (PCT-guided therapy)

Contacts

Public
Dept. of Emergency Medicine, Erasmus MC Rotterdam

Yuri van der Does
Rotterdam
The Netherlands
010-7040704
Scientific
Dept. of Emergency Medicine, Erasmus MC Rotterdam

Yuri van der Does
Rotterdam
The Netherlands
010-7040704

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Fever: ear temperature> 38.1 0C
• Signed informed consent
• Aged 18 years or older

Exclusion criteria

A potential eligible subject who meets any of the following criteria will be excluded from participation in this study:
• Pregnancy.
• Immunocompromised patients (neutropenia, defined as an absolute neutrophil count less than 0.5x109/L, current chemotherapy, transplantation patients).
• Predetermined illness with an expected death within 24 hours.
• Surgical fever, defined as fever within 72 hours post-surgery, or patients with a primary surgical diagnosis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2014
Enrollment:	550
Type:	Actual

Ethics review

Positive opinion

Date:	08-01-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41410
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4826
NTR-old	NTR4949
CCMO	NL44227.078.13
OMON	NL-OMON41410

Study results

Summary results
Procalcitonin guided antibiotic therapy in patients presenting with fever in the emergency department.

Limper M, van der Does Y, Brandjes DP, De Kruif MD, Rood PP, van Gorp EC.

J Infect. 2014 Oct;69(4):410-2

PMID: 24820656