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

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Primary:- To investigate efficacy of PCT-guided antibiotic therapy in the ED- To evaluate the safety of PCT-guided antibiotic therapy in the ED - To determine and compare the accuracy of PCT and CRP as biomarker for bacterial infectionSecondary:- To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41410

Source
ToetsingOnline

Brief title
HiTEMP

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
fever, pyrexia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BIOMARKER, COST-EFFECTIVENESS, FEVER, PROCALCITONIN

Outcome measures

Primary outcome

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

* A composite endpoint for 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 the diagnosis of 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).

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

* 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 extramural type and duration of antimicrobial therapy.

Study description

Background summary

Background: Infectious diseases are an important problem for patients presenting to the emergency department (ED). Timely diagnostic-therapeutic decisions are crucial in many cases and it will have a repercussion in survival of patients with severe bacterial infections. However, clinical features in infectious diseases are often nonspecific, which make early recognition and implementation of adequate therapy difficult. There are several biomarkers of infection that have been investigated in recent years. One of these markers, procalcitonin (PCT), has a good diagnostic utility. The implementation of PCT testing could help tremendously in achieving early diagnosis and adequate management of febrile patients with infectious diseases in the ED.

Rationale: 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. This may lead to a reduction of antibiotics resistance and costs.

Study objective

Primary:
- To investigate efficacy of PCT-guided antibiotic therapy in the ED
- To evaluate the safety of PCT-guided antibiotic therapy in the ED
- To determine and compare the accuracy of PCT and CRP as biomarker for bacterial infection

Secondary:
- To study if PCT-guided therapy is cost-effective

Study design

Multi center randomized study. 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. The primary objective 'accuracy' is designed as a superiority study, where the accuracy of biomarkers in the diagnosis of bacterial infection is determined and compared using an AUC.

Intervention

Patients will be allocated into two groups:

1. A control group (standard-of-care)

2. Intervention group (PCT-guided therapy)

Study burden and risks

This trial is considered a intermediate risk trial as it follows the international surviving sepsis campaign guidelines for PCT- guided therapy. This trial is supported by results of earlier research performed with PCT, in which PCT-guided therapy has shown to be safe in febrile patients. Recent meta-analyses found no increased risk or rate of treatment failure when PCT-guided therapy was used in patients with acute respiratory infections, and found a significant reduction in antibiotic usage across all clinical settings.
The expected benefits are that the implementation of PCT-guided therapy should help in application of adequate (antibiotic) therapy. It will prevent unnecessary antibiotic therapy, which reduces bacterial antibiotic resistance. It will also help in reducing medical costs and the risk of drug related adverse effects.
Furthermore, this study respects physician judgement. In case the physician decides that antibiotics are required, even though the study protocol advises otherwise, this treatment can be initiated regardless of PCT levels.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 30
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 30
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

fever

Exclusion criteria

under 18 years of age. Pregnant patients. 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:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

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

Ethics review

Approved WMO Date:	12-08-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25141
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44227.078.13
OMON	NL-OMON25141