Diagnostic intervention study of low-dose CT and multiplex PCR on antibiotic treatment and outcome of community-acquired pneumonia

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

Summary

ID

NL-OMON48670

Source
ToetsingOnline

Brief title
CAP-NEXT

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
pneumonia;pulmonary infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: Antibiotics, CT, PCR, Pneumonia

Outcome measures

Primary outcome

The primary effectiveness outcome is days of therapy of broad-spectrum antibiotics. The primary safety outcome, on which the sample size is calculated, is 90-day all-cause mortality.

Secondary outcome

- Number of days of treatment with any antibiotics during index admission, including antibiotic prescriptions provided at discharge;
- Number of days hospitalized during the index hospitalization;
- Occurrence of ICU admission during the index hospitalization;
- Occurrence of in-hospital mortality during the index hospitalization;
- Occurrence of readmissions after the index admission within 30 days of the index admission;
- Time from admission to availability of the low-dose CT results;
- Time from admission to provision of a treatment recommendation following the low-dose CT results;
- Proportion of patients changing the diagnosis based on low-dose CT results;
- Time from admission to change in diagnosis based on low-dose CT results;
- Time from presenting at the ER to availability of the PoC-PCR test results;

- Time from presenting at the ER to provision of a treatment recommendation following the PoC-PCR test results;

- Proportion of patients changing from empirical to or started on targeted antibiotic treatment based on PoC-PCR results;

- Proportion of patients stopping empirical antibiotic treatment early (within 72 hours) based on PoC-PCR results;

- Time from admission to targeted antibiotic treatment or early termination based on the PoC-PCR results;

Study description

Background summary

Uncertainty in the clinical and etiological diagnosis of community-acquired pneumonia (CAP) often leads to incorrect treatment and unnecessary use of broad-spectrum antibiotics. Establishing the clinical diagnosis of CAP is hampered by the suboptimal sensitivity of chest radiograph to detect pulmonary infiltrates (~70%). Establishing the etiological diagnosis is also hampered, mainly because of the inevitable diagnostic delays and low sensitivity of routine microbiological tests. There are currently no recommendations for low-dose chest computed tomography (low-dose CT) or point-of-care multiplex polymerase chain reaction (PoC-PCR) in the diagnostic work-up of CAP patients, because the data supporting such an approach are lacking.

Study objective

The aim of this study is to determine the added value of low-dose CT and PoC-PCR in the diagnostic workup of patients with CAP hospitalised to non-intensive care unit (ICU) wards in minimizing selective antibiotic pressure while maintaining patient safety.

Study design

Cluster-randomised controlled trial with historical control period.

Intervention

Intervention arm 1: availability of PoC-PCR during the ER visit; intervention arm 2: performing low-dose CT from the ER or at least within 24 hours; control arm: standard care.

Study burden and risks

There are no risks associated with performing the PoC-PCR and the radiation of the low-dose CT is of negligible risk. Nasopharyngeal swab collection causes a temporary unpleasant sensation. The low-dose CT can reveal unexpected findings which may require additional diagnostic procedures, for which the treating physician will use state-of-the-art guidelines. Treatment recommendations to de-escalate or stop antibiotic treatment may be beneficial for the individual patient by minimising exposure to antibiotics and improve targeted use of antibiotics. Final decisions are always made by the treating physician taking into account all clinical information.

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

- Being aged 18 years or above;
- Having a working diagnosis of CAP at the emergency department with the presence of at least two of the clinical criteria (below)* or one clinical criterion and radiological evidence of CAP, with no other explanation for the signs and symptoms;
- Requiring hospitalisation to a non-ICU ward via the ER., * Clinical criteria include:
* New or worsened coughing;
* Production of purulent sputum or change in character of sputum;
* Temperature > 38°C or <<= 36.0°C;
* Auscultatory findings consistent with pneumonia, including rales, evidence of pulmonary consolidation (dullness on percussion, bronchial breath sounds, or egophony), or both;
* White blood cell count of >10×10^9 cells/L or <4x10^9 cells/L or >15% bands
* C-reactive protein level ><= 30 mg/L;
* Dyspnea, tachypnea (> 20 breaths per minute), or hypoxaemia (arterial pO2 <60 mmHg or peripheral O2 saturation < 90%).

Exclusion criteria

- Hospitalisation for two or more days in the last 14 days;
- Residence in a long-term care facility in the last 14 days;
- History of cystic fibrosis;
- Severe immunodeficiency, defined as having one or more of the following criteria:
* HIV infection with a last CD4 count of <300/*L;
* Cytotoxic chemotherapy or radiotherapy in the previous 3 months;
* Chronic hemodialysis > 3 months;
* History of receiving an organ or bone marrow transplant;
* Using immunosuppressive therapy. This includes corticosteroid treatment only when dosage is high (>0,5mg/kg/day) for a longer period of time (>14 days).
* History of primary immunocompromising conditions

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2017
Enrollment:	3760
Type:	Actual

Ethics review

Approved WMO Date:	11-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-11-2019
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NCT03360851
CCMO	NL61857.041.17