Neutrophil granulocyte membrane-based biomarker discovery for discrimination between acute bacterial versus acute viral infection: a pilot study.

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Identification of host biomarkers, being membrane bound proteins, on both neutrophils and CD64 expressing cells, that have discriminatory difference in concentrations.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49203

Source
ToetsingOnline

Brief title
Levels study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Bacterial and viral respiratory infections

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Levels Diagnostics BV

Intervention

Keyword: Bacterial infection, Biomarkers, Proteoma, Viral infection

Outcome measures

Primary outcome

Membrane bound proteins (biomarkers) on neutrophils and CD64 expressing cells.

(spectrum of proteins as determined by proteomics)

Secondary outcome

Analysis of previously studied serum markers CRP and IP-10 using a rapid Point

of Care (POC) lateral flow test and multiplex cytokine analysis

Study description

Background summary

At present, it is often difficult to immediately diagnose the cause of an infection as being bacterial or viral. Laboratory tests based on measurement of C-Reactive Protein (CRP) and other serum proteins currently do not reach the discriminatory power to accurately diagnose a bacterial infection in clinical settings. Under many other circumstances these markers can be elevated while there is no bacterial infection present. Therefore, it is necessary to investigate novel biomarkers that have the capacity to detect and rule out bacterial infection at the time the patient first presents with a suspected infection at the emergency room or in the clinic. By doing so, the overuse of antibiotics can be prevented. In addition, growing resistance of microorganisms, adverse reactions to antibiotics and increasing health-care costs can be averted. The overall aim of Levels Diagnostics, a startup company, in cooperation with medical specialists from Leiden University Medical Center (LUMC) and the Center for human drug research (CHDR) is to develop a rapid diagnostic tool that can detect a bacterial infection by using host cell (neutrophils and CD64+ cells) membrane bound proteins, specific for bacterial infections. By offering a reliable diagnostic tool it will become possible to enforce a policy restricting the use of antibiotic medication without risks for the patients. This study is the first (pilot) clinical study.

Study objective

Identification of host biomarkers, being membrane bound proteins, on both neutrophils and CD64 expressing cells, that have discriminatory difference in concentrations.

Study design

Non-interventional cohort study of 30 participants with acute bacterial infections (N=10), acute viral infections (N=10) and healthy participants (N=10).

Study burden and risks

At the time of clinical presentation, viral respiratory infections are hard to distinguish from bacterial infections due to similar symptoms. As a result, antibiotics are often prescribed to patients with a viral infection, fuelling antibiotic resistance, increasing public health costs and unnecessary side effects. The aim of the study is to identify novel membrane-bound biomarkers that are specifically associated with bacterial infections and hence could allow a reliable diagnosis. The outcome of this study could contribute to the development of next generation biomarker tests, which in turn enable better targeted antibiotic prescriptions, greatly benefiting patients.

The proposed biomarker search is performed on two EDTA blood tubes and 1 clothing tube drawn from healthy participants and participants suspected of acute viral or bacterial respiratory infections. Participating in the study will not add discomfort to the patient as blood samples will be taken as part of routine procedure if possible, or taken by venipuncture with only the risk of (minimal) skin bruising. There are no other risks associated with the participation in this study.

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

Patients: Adult (18 or above) participants with a suspected respiratory tract
infection (pneumonia defined as respiratory complaints) presenting with fever
(Temperature >37.7), at the Leiden University Medical Center, who will be
admitted to the hospital, mentally competent., Healthy controls: adult (18 or
above), temperature <37.5, no suspected infection

Exclusion criteria

Relation with the PI or the relevant department
The participant is under treatment of immunosuppressive agents and/or
antihistamines
The participant is treated with chemotherapeutics
The participant is treated with intravenous medication
The participant has leukopenia (<2.5 leukocyten x10^9/L)
The participant has used antibiotics (one or more tablets, in the past 48 hours
or chronically)
Participants who are on corticosteroid treatment (inhalers included)
Participants who suffer or have suffered from diseases affecting bone marrow
functio or after stem cell transplantation
Hemato-oncologic patients
Terminal patients (prognosis <6 months)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2019
Enrollment:	44
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-02-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL67474.058.18