

the role of risk factors on the host-pathogen interactions in melioidosis

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Ethical review	Approved WMO
Status	Pending
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON51780

Source

ToetsingOnline

Brief title

RHIME

Condition

- Immune disorders NEC
- Hepatobiliary neoplasms malignant and unspecified

Synonym

Burkholderia pseudomallei infection, Melioidosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Comorbidities, Diabetes, Host-pathogen interactions, Melioidosis

Outcome measures

Primary outcome

We will outline the differences in macrophage function, specifically phagocytosis, bacterial killing, and cytokine response, in those at higher risk of acquisition due to underlying comorbidities in melioidosis.

Secondary outcome

To delineate the underlying processes, such as gene expression and immuno-metabolic profiles, to understand altered macrophage function.

Study description

Background summary

Melioidosis is a severe, emerging infectious disease caused by the bacterium *Burkholderia pseudomallei*. It is widespread across the tropics, contributing to high burden of community acquired sepsis (mortality ~40%) in some regions. The majority of patients suffering from melioidosis have underlying risk factors, most notably diabetes, renal failure, liver failure and thalassemia. Of interest, HIV is not considered to be a risk factor for melioidosis. However, despite prior work, there is still a lack of understanding on the cellular immune responses in human melioidosis and patients with diabetes (12-fold heightened risk) or other comorbidities.

Study objective

This study aims to delineate the alterations in leukocyte function during ex-vivo host-pathogen interactions. These data will be correlated with several factors such as coexisting comorbidities (e.g. diabetes) and functional defects analyzed using ex-vivo stimulation models for cytokine production, phagocytosis, and bacterial killing.

Study design

Observational study using ex vivo stimulation models of whole blood, PBMCs and single cells, isolated from patients with underlying comorbidities recruited in outpatient clinics of the Amsterdam UMC, location AMC.

Study burden and risks

The risks are negligible (associated with venepuncture) and the burden is minimal. 50 ml of blood will be taken in a single visit. A very short questionnaire will be filled in to reduce confounders. The study is group related as these are the underlying risk factors for the disease in epidemiological studies. As majority of patients will be recruited from outpatient clinics, they will already have routine examinations and parameters recorded.

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

adult patient with one of the following comorbidities:

- Type II Diabetes (8% (182 mg/dL) < HBA1c >=8.0% (183 mg/dL);poorly controlled),
- HIV-1 (200<= CD4 count >200),
- Renal failure (eGFR < 30 or on dialysis)
- Liver failure (Child-Pugh score A,B or C)
- Thalassaemia (with and without iron overload)
- COPD (2 < GOLD > 3/4).

Exclusion criteria

Patients < 18 years. Patients with immunosuppressive medication, a recent infectious syndrome, or recent vaccination (within 30 days) will not be included.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	10-06-2022
Enrollment:	140
Type:	Anticipated

Ethics review

Approved WMO

Date: 05-08-2022

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL80936.018.22