Perpetual Observational Study - Disease X

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Primary objectives:- To prospectively study and describe the aetiology, clinical management and clinical impact of atypical viral infections in immunocompromised patients in Europe- To assess the utility of metagenomics as a tool to support clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immunodeficiency syndromes
Study type	Observational invasive

Summary

ID

NL-OMON56167

Source
ToetsingOnline

Brief title
POS-DiseaseX

Condition

- Immunodeficiency syndromes
- Viral infectious disorders

Synonym
outbreaks, viral infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: emerging viruses, infectious disease, metagenomics

Outcome measures

Primary outcome

- Description of the clinical characteristics and aetiologies of infectious syndromes among the patients included in the POS;

- Analysis of variations in local practices in diagnosis and treatment of Disease X among study sites;

Secondary outcome

- Characterization of intra-host viral evolution among immunocompromised patients with persistent viral infections;

- Development of an infrastructure for prospective and systematic collection of data and clinical samples in a format that can be easily aggregated, tabulated and analysed across different participating centres;

Study description

Background summary

The COVID-19 pandemic has shown that sustained international multi-centre observational studies and clinical trial platforms are required to reduce the impact of emerging infectious diseases. ECRAID (European Clinical Research Alliance for Infectious Diseases)-Base is a European consortium with the aim to build a network for clinical research studies in the field of infectious diseases that is ready to pivot to studies of new infectious diseases (emerging infectious diseases, EID) if they arise. Work package 5 of ECRAID-Base is led by the Department of Viroscience of EMC and will assess the use of a generic protocol for inclusion of patients into an observational study for any clinical syndrome of suspected unexplained infectious aetiology. Through this, we aim to decrease the time to roll-out of an observational study in an emergency situation for any rare or novel infectious disease. This so-called warm-based

study initially focuses on immunocompromised patients presenting to the hospital with a suspected viral infection not caused by any of the most commonly observed pathogens, or with a known viral infection with an atypical clinical presentation. The rationale for this choice is that immunocompromised individuals have an increased risk of developing persistent infection and of acquiring infections with unusual pathogens. In addition, these patients have been hypothesized to be a source of emerging virus variants with enhanced transmissibility, immune escape, changed disease severity, or viruses that have developed genetic resistance to antiviral treatment. Here we study viral infections among immunocompromised patients focusing on the aetiology of infectious disease syndromes, risk factors, and within-host viral evolution. This will be combined with the use of novel techniques (i.e. metagenomics) for catch-all diagnostics among participating sites and establishes a European clinical research network for diagnostic trials.

Study objective

Primary objectives:
- To prospectively study and describe the aetiology, clinical management and clinical impact of atypical viral infections in immunocompromised patients in Europe
- To assess the utility of metagenomics as a tool to support clinical decision making
- To improve laboratory diagnosis of - and preparedness for emerging viral infections

Secondary objectives:
- To develop a clinical research network for responding to any emerging pathogen
- To study intra-host viral evolution in the immunocompromised host

Study design

Prospective perpetual observational study (POS)

Study burden and risks

This study entails minimal harm for the study participants. In rare cases, venipuncture can lead to complications such as hematoma or infection.

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

A) >18 years old
B) Suspected infectious illness without a clear aetiology upon initial clinical evaluation
C) Immunocompromised (Solid organ transplant recipient, OR received anti-C20 therapy in the past 9 months, OR primary immunodeficiency disorder)
D) Symptom onset <7 days

Exclusion criteria

A) Detection of a non-viral infectious agent that can explain the symptoms
B) Surgery or Intensive Care admission in the last 30 days
C Treatment with cytotoxic antineoplastic therapy in the last 30 days
D) Symptoms of urinary tract infection

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2023
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-12-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL83193.078.23