Introducing point-of-care ultrasound at the bedside for diagnosing opportunistic diseases in patients with HIV

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We aim to determine the feasibility and diagnostic value of POCUS in detecting opportunistic disease in HIV patients with advanced disease stages in the Netherlands.

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49983

Source
ToetsingOnline

Brief title
Point-of care ultrasound for patients with HIV

Condition

- Viral infectious disorders

Synonym
HIV, immune deficiency cauased by viral infection

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: AIDS fonds

Intervention

Keyword: HIV, Opportunistic disease, Ultrasound

Outcome measures

Primary outcome

Our primary outcomes include acceptability of POCUS by patients, interobserver variation in interpretation of POCUS images, and number of diagnosed AIDS and non-AIDS related problems.

Secondary outcome

Secundary outcomes include sensitivity and specificity, negative predictive value and positive predictive value of our POCUS protocol. In addition, incidence rates of opportunistic infections will be compared to a historical matched control group.

Study description

Background summary

Point-of-care ultrasound (POCUS) is increasingly used by various specialists in the Netherlands, but its role in managing patients with HIV is unclear. In settings endemic for tuberculosis, Fast Assessment with Sonography for HIV/TB (FASH) has proven its value to detect extrapulmonary tuberculosis in patients with HIV. However, there is no data to support POCUS for patients with HIV in resource affluent settings.

Study objective

We aim to determine the feasibility and diagnostic value of POCUS in detecting opportunistic disease in HIV patients with advanced disease stages in the Netherlands.

Study design

We will perform a prospective observational pilot study

Study burden and risks

The ultrasound examination is painless and without risk to the participants. It will take approximately 30 minutes and will be combined with routine visits to the hospital. Benefits include potential earlier detection of opportunistic disease, while adverse effects may arise from false positive findings requiring further examinations which may cause stress or anxiety. The rate of false positive findings in POCUS has not been formally investigated, but appears low. The effect of POCUS in advanced HIV/AIDS can only be studied in HIV patients.

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 newly presenting with HIV to the outpatient clinic with a CD4 T-cell count below 350 cells/mm3, and all patients with HIV requiring admission to hospital.

Exclusion criteria

Absence of informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	37
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2020
Application type:	First submission
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	NL72666.078.20