Long-term outcomes of pulmonary function in HIV-infected patients with a history of Pneumocystis jirovecii pneumonia

Published: 11-05-2020
Last updated: 08-04-2024

Assessing the prevalence of pulmonary function testing abnormalities in HIV-infected patients with and without a history of PJP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protozoal infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55803

Source
ToetsingOnline

Brief title
Pulmonary function after PJP in HIV

Condition

- Protozoal infectious disorders

Synonym
gas transport disorder in the lungs, Pneumocystis Jirovecii Pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Gilead Sciences

Intervention

Keyword: HIV, PJP, Pulmonary function

Outcome measures

Primary outcome

The prevalence of abnormalities in pulmonary function testing like obstructive or restrictive lung disease and CO diffusion impairment. The following parameters will be assessed: Vital capacity, Forced Expiratory Volume in 1 second (FEV1) and carbon-dioxide diffusion capacity.

Secondary outcome

1. to establish if the prevalence of obstructive ventilatory disorder in HIV infected patients with a history of PJP is significantly higher than in the HIV positive matched controls;

2. to establish if the prevalence of restrictive ventilatory disorder in HIV infected patients with a history of PJP is significantly higher than in the HIV positive matched controls;

3. to establish if there is relation between diminishing of de pulmonary diffusion capacity and the self-reported pulmonary complaints;

4. to establish if the self-reported pulmonary complaints are more prevalent in the group of HIV patients with history of PJP compared to matched controls.

Study description

Background summary

In the early years of the HIV-epidemic, Pneumocystis jirovecii pneumonia (PJP) was one of the leading causes of morbidity and mortality in HIV-infected

patients. One of the most significant features of PJP is the severe impairment of the pulmonary diffusion capacity, which was also used to establish the diagnosis. The introduction of effective combined antiretroviral therapy (cART) has led to a dramatic improvement in the survival of HIV-infected patients with opportunistic infections, and also of those with PJP. However, it is unclear whether the diffusion capacity completely resolves after completing of the antimicrobial therapy directed against Pneumocystis.

In the University Medical Centre Utrecht, approximately 50 HIV-positive patients with a history of PJP underwent pulmonary function testing as a matter of routine care. The presence of persistent impaired diffusion capacity was frequently encountered in these patients. However, it is unclear what the background prevalence of diffusion impairment in the general HIV-positive population in the Netherlands is. In order to draw conclusions from the earlier observations, we are planning to set-up a cohort of HIV-positive controls without a history of PJP that are matched by age, gender, nadir CD4 cell count, time since HIV diagnosis and smoking history with the historical cohort.

Patients from the historical cohort will be approached to give consent for the use of the earlier data.

Study objective

Assessing the prevalence of pulmonary function testing abnormalities in HIV-infected patients with and without a history of PJP.

Study design

Observational cohort study

Study burden and risks

Patients without a history of PJP: The burden of research for these patients is very limited. The study consists of two parts. First, the patient is contacted twice by phone: the first phone call to explain the study, after which the patient (after consenting) is sent information pertaining to the study to his home address. The second phone call will be made after two weeks in order to answer remaining questions about the study and to ask whether the patient wants to participate (in which case he will sign and return the sent informed consent forms). Second, the patient will undergo pulmonary function testing - which takes approximately 40 minutes. There are no health or safety risks related to the pulmonary function testing.

Only the group without history of PJP will undergo a pulmonary function testing. In the group of patients with history of PJP, the results of the

routinely performed pulmonary function tests will be used. These patients will also be called twice for recruitment and consent, via the same procedure as described above.

With respect to the patients who already underwent pulmonary function testing, the burden is also limited. They will only be approached for consent to use the data of the earlier pulmonary function tests.

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

HIV-infected patients with and without a history of Pneumocystis Jirovecii Pneumonia

Exclusion criteria

* Active pulmonary infection or cardiac decompensation at the moment of pulmonary function testing
* Chronic condition which could influence the pulmonary function testing
* Unexplained dyspnoea, tachypnoea or other acute respiratory complaints at the moment of pulmonary function testing (<3 weeks of duration)
* In the opinion of treating physician, not being able to cooperate during the pulmonary function testing.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2020
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	14-05-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL62009.041.20