NAFLD and NASH in HIV-patients, prevalence and risk factors.

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Primary objectives: 1. . To study prevalence of NASH in unselected HIV-monoinfected patients assessed by Fibro scan. Secondary objectives:2. To identify risk factors for NASH in HIV infected patients compared to HIV-positive patients without NASH. 3...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON46464

Source
ToetsingOnline

Brief title
NAFLD and NASH in HIV-patients

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
fatty liver, liver steatosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: HIV, NAFLD

Outcome measures

Primary outcome

1. Prevalence of NASH in our HIV-infected population compared to what is known

from other HIV populations (6-11%).

Secondary outcome

2. Risk factors for NASH

3. Prevalence of NALFD in our HIV-infected population compared to what is known

from other HIV populations (30-55%).

4. Risk factors for NALFD

Study description

Background summary

Non-alcoholic fatty liver disease (NAFLD) refers to hepatic steatosis in individuals with little or no alcohol use. A subgroup of NAFLD patients develops non-alcoholic steatohepatitis (NASH), defined by the presence of inflammation in addition to steatosis, with a risk of developing liver cirrhosis or hepatocellular carcinoma. Some recent studies that investigated the causes of transaminitis among HIV-infected patients showed NAFLD to be the most common cause (up to 60%)7-9. Recognition and staging of NAFLD should be part of the metabolic monitoring of all patients with HIV. Life style intervention (diet and exercise) remains the most important strategy to lower prevalence of NASH and NALFD and should be cornerstone of NAFLD treatment 30,31.

Study objective

Primary objectives:
1. . To study prevalence of NASH in unselected HIV-monoinfected patients assessed by Fibro scan.

Secondary objectives:
2. To identify risk factors for NASH in HIV infected patients compared to HIV-positive patients without NASH.
3. To study prevalence of NALFD in unselected HIV-monoinfected patients assessed by Fatty Liver Score and CAP.
4. To identify risk factors for NALFD in HIV-positive patients compared to HIV-positive patients without NAFLD.

Study design

Observational cross sectional study in HIV-infected patients to access the rate of and risk factors for NAFLD and NASH. Sample size: n=740 patients. Duration: 1 year.

All out clinic patients with HIV of the department of infectious diseases are offered a fibro scan with CAP-measurement and an short questionnaire regarding to risk factors for fatty liver disease. See page 9 for criteria and page 14 for study procedures.

Intervention

Fibroscan + CAP measurement.

The fibroscan non-invasively measures the elasticity of the liver, allowing the degree of fibrosis to be determined. With the same device a CAP measurement is performed, also called Controlled Attenuation Parameter: a non-invasive measurement for liver steatosis

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
A study-related fibroscan could be a burden to patients, not because of the non-invasive, fast and painless procedure, but because of the possible outcome (steatosis, fibrosis or other pathology which otherwise would have stayed unknown). And because of these possible outcome, referral to a hepatologist could be needed to support clinical management.

However earlier diagnosis of NAFLD and especially NASH could lead successful implementation of life style interventions and secondary prevention of further progression of disease to cirrhosis and HCC. That is why we think the benefits of participating in this study outweighs the burden and risks.

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

Unselected adult HIV-infected patients visiting the outpatient clinic of a major HIV reference centers in the Netherland (Erasmus MC).

Exclusion criteria

* Excessive alcohol consumption (> 5 glasses per day)
* (History of) hepatocellular carcinoma
* Liver transplant in the past
* Contraindications fibroscan (pregnancy, pacemaker)
* Other liver diseases (autoimmune hepatitis, hemochromatosis, Wilson's disease).
Note: Chronic hepatitis B and C are not exclusionary criteria.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-05-2018
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	NL63141.078.17