

Characterization of hepatic lymphocytes in patients with viral hepatitis and other liver diseases.

Published: 12-01-2012

Last updated: 01-05-2024

To study phenotypic and functional characteristics of hepatic lymphocytes in patients with viral hepatitis or other liver related diseases.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON47692

Source

ToetsingOnline

Brief title

Characterization of hepatic lymphocytes

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym

chronic hepatitis B, chronic hepatitis C, viral liverdisease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: AMC

Intervention

Keyword: immunology, liver lymphocytes, viral hepatitis

Outcome measures

Primary outcome

To phenotypically and functionally analyze liver and peripheral T cells in patients with viral hepatitis and other liver diseases in order to get more insight in immune system in the liver. Patients with viral hepatitis will be compared with patients with a non-viral liver related disease.

Secondary outcome

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Study description

Background summary

The mechanism of developing chronic hepatitis B and chronic hepatitis C, rather than clearing acute infection, is not fully understood but is likely multifactorial. Both chronic hepatitis B and C infection are associated with impairment of the innate and adaptive immune responses and are associated with narrow and weak T cell responses. The function of T cells in viral hepatitis has largely been obtained by studying low numbers of peripheral blood T cells. However, as hepatitis C and hepatitis B are hepatotropic viruses, virus-specific T cells accumulate in the human liver. Due to different homeostatic circumstances and antigen environment in the target organ, residing T cells may have altered functional characteristics and phenotype. As such little is known about general and virus-specific immune responses in the liver.

The aim of this study is to investigate the T cell immune system in the liver which could provide insights into mechanisms of failure of viral control and/or the development liver damage.

Study objective

To study phenotypic and functional characteristics of hepatic lymphocytes in

patients with viral hepatitis or other liver related diseases.

Study design

This is an interventional study with a once-only intervention of blood collection performed in patients that undergo a liverresection or transplantation. Of the resected specimen 5-15 gram of liver tissue, redundant for pathological/histological investigation, will be used for analysis.

Intervention

Patients that are included in the study will donate 5 tubes of 9 ml blood once only 1-2 weeks before surgery.

Study burden and risks

Potential physical discomfort associated with participation are the burden of in total 69 ml of blood samples that will be taken once-only. These samples will be taken when the patient is admitted to hospital and awaiting surgery. The liverspecimen used for this study will by no means alter or influence surgery procedures or outcome. Only tissue redundant for pathologic examination will be used (this tissue had to be removed as part of the surgery).

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 between 18-65 year old that undergo a liverresection.

Exclusion criteria

Unwillingness to donate blood

Co-infection with HIV (if known)

(a HIV test is not required for participation in the study)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 02-01-2012

Enrollment: 40

Type: Actual

Ethics review

Approved WMO	
Date:	12-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-02-2019
Application type:	Amendment
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	NL38694.018.11