T cell function in acute hepatitis B virus infection

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The aim of this study is to investigate the T cell immune system in relation to viral kinetics in acute HBV infection in order to obtain more insight into mechanisms of failure of viral control and development of chronic HBV infection, and to...

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

Summary

ID

NL-OMON38638

Source
ToetsingOnline

Brief title
T cell function in acute HBV infection

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
acute liver infection with hepatitis B virus ; acute viral infection with hepatitis B virus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute HBV infection, HBV immunology, HBV specific T cell response, hepatitis B

Outcome measures

Primary outcome

Primary objective: to define the immunologic and virologic signature of acute hepatitis B patients by longitudinally studying the phenotypic and functional characteristics of peripheral blood mononuclear cells (PBMC*s) and HBV viral kinetics. Patients with acute HBV infection will be compared to patients with chronic HBV infection (with high and low viral load).

Secondary outcome

Secondary objective: to investigate the mechanism of development of chronic HBV infection by comparing patients with acute HBV infection in patients clearing the HBV within 6 months versus patients who develop chronic HBV infection.

Study description

Background summary

The mechanism of developing chronic hepatitis B virus (HBV) infection, rather than clearing acute infection, is not fully understood but is likely multifactorial. The ability to control (and clear) an acute HBV infection is thought to be related to the balance between the quantity of infected hepatocytes and the efficiency of the T-cell response. This T cell response may be attenuated by several factors that could be divided into self-save mechanisms and viral escape through upregulation of different cytokines. Development of chronic hepatitis B infection is associated with impairment of the innate and adaptive immune responses and with narrow and weak T cell responses. It remains a question of debate whether the impairment of T cell responses are a cause or consequence of persistent infection.

Study objective

The aim of this study is to investigate the T cell immune system in relation to viral kinetics in acute HBV infection in order to obtain more insight into mechanisms of failure of viral control and development of chronic HBV infection, and to compare our findings with data already obtained in chronic hepatitis B patients with either high and low viral load.

Study design

Observational study with multiple interventions of blood collection (6 times during 1 year)

Study burden and risks

The burden associated with participation is that of obtaining blood samples six times during a period of 1 year. This will be as much as possible combined with blood sampling for routine HBV diagnostic tests (at least 2 times). There will be additional visits (and venipunctures) required of at most three times. The total amount of collected blood is 575 mL (including blood collected for routine diagnostic tests), which will be collected over six times during 1 year, with a maximum of 102 mL per time. Extra sampling will be 62 ml to 69.5 ml per time, wih a total of 379,5 ml in total.

The risk of participation is only the risk associated with the procedure of additional venipuncture (maximum of 3 times extra), being redness of the skin, pain or hematoma at the area of the puncture.

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 that will be included are:
- patients who present to the AMC or to the AMC outpatient clinic location GG&GD Amsterdam with an acute hepatitis B infection;
- patients formerly diagnosed (at the AMC) with an acute HBV infection (within the last 5 years) and from whom blood samples for viral diagnostics at several time points were collected.

Exclusion criteria

Unwillingness to donate blood and/or sign an informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2013
Application type:	First submission
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	NL45101.018.13