Cohort of hepatitis B research in Amsterdam.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21330

Source
Nationaal Trial Register

Brief title
COBRA

Health condition

cirrhosis, hepatitis B virus, hepatocellular carcinoma, viral load

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Public Health Service (GGD) Amsterdam
Source(s) of monetary or material Support: Gilead

Intervention

Outcome measures

Primary outcome

Main study parameters are any of following complications:

1. Liver cirrhosis;

2. Death related to HBV morbidity.

Secondary outcome

Secondary study parameters are:

1. HCC;

2. Liver transplantation;

3. End-stage liver disease (Child-Pugh B or C);

4. Viral load of hepatitis B (comparison of historic and follow-up serum samples);

5. Parameters of activation, exhaustion and apoptosis in various subsets of immunological cells.

Study description

Background summary

Hepatitis B is a form of liver disease caused by a DNA-virus, called hepatitis B virus (HBV). Infection can result in an inflammation of the liver parenchyma with various clinical manifestations ranging from an asymptomatic course to jaundice. After contact with the virus the immunological response of the host determines the clinical outcome leading to either viral clearance or a chronic infection.

Although several factors are responsible for the development of chronic HBV-infection, one of the factors is a weak and transient CD8+ T-cell responses after HBV infection. In chronic hepatitis B, inflammation can lead to scarring which is the driving force to fibrosis and cirrhosis. Some immunological parameters, like a newly discovered subset of IL-17 producing T helper cells (Th17 cells), may influence the disease progression of HBV. In the cirrhotic patient, eventually there is an increased risk of hepatocellular carcinoma (HCC) leading to liver failure.

Recent literature in Asian patients with chronic hepatitis B showed that serum HBV viral load is a strong predictor for the development of cirrhosis, independent of hepatitis B e antigen status and serum alanine transaminase level. It is unclear whether these results can be extrapolated to non-Asian (Caucasian and African) populations because of differences in host (HLA background) and viral (HBV genotype) factors.

The aim of this study is to elucidate the question whether historic HBV viral load (insamples taken from 1989 - 1996 during pregnancy) is associated with the risk of HBVrelated cirrhosis or mortality in a cohort of non-Asian individuals with chronic hepatitis B infection.

Study objective

The aim of this study is to elucidate the question whether historic HBV viral load (in samples taken from 1989 – 1996 during pregnancy) is associated with the risk of HBVrelated cirrhosis or mortality in a cohort of non-Asian individuals with chronic hepatitis B infection.

Study design

Historic (more than 15 years ago) bloodsample compared to present bloodsample.

Intervention

1. Venapunction;

2. Fibroscan;

3. Health assessment questionnaire.

Contacts

Public
P.O. Box 85500, F02.126
S. Harkisoen
Department of Internal Medicine & Infectious diseases
University Medical Center Utrecht
Heidelberglaan 100
Utrecht 3508 GA
The Netherlands
+31 (0)88 7555555
Scientific
P.O. Box 85500, F02.126
S. Harkisoen
Department of Internal Medicine & Infectious diseases
University Medical Center Utrecht
Heidelberglaan 100
Utrecht 3508 GA
The Netherlands
+31 (0)88 7555555

Eligibility criteria

Inclusion criteria

1. HBsAg-positivity;

2. Serum sample available from the screening programme at the Public Health Service;

3. Still living and alive in Amsterdam or Diemen and address traceable by general practitioners or municipal authorities;

4. Non-Asian (both parents not born in Asia);

5. Between 18-65 years old;

6. Capable of giving informed consent and capable of traveling to the Public Health Service.

Exclusion criteria

1. Subjects coinfected with human immunodeficiency virus (HIV), hepatitis D virus (HDV) or hepatitis C virus (HCV);

2. Subjects who are unable to come to the outpatient clinic;

3. Subjects incapable to give informed consent due to legally incompetence.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2011
Enrollment:	172
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36693
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2889
NTR-old	NTR3035
CCMO	NL34329.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36693

Study results

Summary results
N/A