Cohort of hepatitis B research in Amsterdam.

Gepubliceerd: 24-08-2011 Laatst bijgewerkt: 15-05-2024

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21330

Bron
Nationaal Trial Register

Verkorte titel
COBRA

Aandoening

cirrhosis, hepatitis B virus, hepatocellular carcinoma, viral load

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Public Health Service (GGD) Amsterdam
Overige ondersteuning: Gilead

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameters are any of following complications:

1. Liver cirrhosis;
2. Death related to HBV morbidity.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

1. Venapunction;

2. Fibroscan;

3. Health assessment questionnaire.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2011

Aantal proefpersonen:	172
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36693
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A