The long-term follow-up interferon-α treatment for chronic hepatitis B infection

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To study the long-term effects of interferon-α treatment for chronic hepatitis B patients infection.

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

Summary

ID

NL-OMON43380

Source
ToetsingOnline

Brief title
ELITE-B study

Condition

- Hepatic and hepatobiliary disorders

Synonym
Chronic hepatitis B infection

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: Stichting Leveronderzoek

Intervention

Keyword: (Peg)interferon treatment, Chronic hepatitis B infection

Outcome measures

Primary outcome

Functional cure of hepatitis B infection: loss of Hepatitis B surface Antigen

+/- seroconversion to anti-HBs positivity.

Secondary outcome

- Initial response: HBeAg loss within 12 months of the end of IFN therapy

- Sustained response: no requirement for retreatment between the time of

initial response and the end of follow-up

- Serologic response at the end of follow-up:

o HBeAg loss +/- seroconversion

- Virological response at the end of follow-up

o HBV DNA <2,000 IU/mL

o HBV DNA <20 IU/mL (complete viral suppression)

- Combined response at the end of follow-up

o HBeAg loss +/- seroconversion & HBV DNA <2,000 IU/mL

o HBeAg loss +/- seroconversion & HBV DNA <20 IU/mL

- Biochemical response at the end of follow-up

o Normal ALT

- Death

- Liver-related death

- Liver transplantation (LTx)

- Hepatocellular carcinoma (HCC)

- Liver decompensation (LD; variceal bleeding, ascites, and/or hepatic encephalopathy)

Study description

Background summary

Several meta-analyses have described that interferon-α treatment for chronic hepatitis B infection reduces hepatitis B-related morbidity and mortality, but these studies have analyzed the results of studies of which the median follow-up duration does not exceed 10 years. It is essential to obtain additional information regarding durability of response, functional cure, and CHB-related events occurring over 10 years after treatment, as increasing age and longer duration of infection are important risk factors for HCC and other HBV complications.

Study objective

To study the long-term effects of interferon-α treatment for chronic hepatitis B patients infection.

Study design

Combination of a retrospective cohort study, with transsectional prospective data-collection in a minority of patients. Only patients who have been discharged from medical follow-up in the past will be invited for a single visit to our clinic for medical history taking and blood withdrawal. Some patients will be asked for written informed consent to draw additional blood during this particular procedure of venepuncture.

Study burden and risks

The study parameters are already available in almost all patients who have been treated per protocol in previous studies, or who are still being treated within a standard of care setting. Patients will be asked to donate blood only if ALT and/or the virologic parameters are older than 6 months. The risks for these subjects are related to blood withdrawal, and concern possible local bruising and low risk of local infection. There is no direct benefit for the subjects.

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

- Chronic hepatitis B infection, defined as HBsAg positivity >=6 months

- Interferon-α (conventional, or peginterferon-α) treatment between 1978 and 2014

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study for analysis of the endpoints of morbidity and mortality only:
- patients who have been diagnosed with hepatitis C (HCV), hepatitis delta (HDV) or human immunodeficiency virus (HIV) coinfection , as coinfections are associated with more severe liver disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2016
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	NL56347.078.15