SUSTAINED RESPONSE TO NUCLEO(S)TIDE ANALOGUES FOR CHRONIC HEPATITIS B: SNAP STUDY

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study outcome and predictors of sustained response in chronic hepatitis B patients who discontinue entecavir or tenofovir

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50717

Source
ToetsingOnline

Brief title
SNAP

Condition

- Viral infectious disorders

Synonym
hepatitis B

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting voor Lever- en Maag- Darm Onderzoek;Rotterdam

Intervention

Keyword: entecavir, hepatitis B, tenofovir

Outcome measures

Primary outcome

sustained response (HBV DNA <2,000) at week 48 after discontinuation.

Secondary outcome

1. Long-term sustained response, defined as HBV DNA < 2,000 IU/mL at week 96

after therapy discontinuation.

2. Need for retreatment (according to study protocol or treating physician)

3. HBsAg clearance at week 48 and 96

4. Occurrence of signs of liver failure (bilirubin > 1.5 x the upper limit of

normal and/or INR > 1.5)

5. Relationship between sustained response at week 48 and 96 and serum levels

of HBsAg at the time of treatment cessation

6. ALT levels at week 48 and 96

7. Fibroscan value at week 96

Study description

Background summary

Longterm antiviral treatment for chronic hepatitis B with entacavir or tenofovir is effective but also associated with mounting costs and potential side effects. Discontinuation of treatment in patients with long-term viral suppression appears to be safe and is associated with sustained response in 30 * 50%.

Study objective

study outcome and predictors of sustained response in chronic hepatitis B patients who discontinue entecavir or tenofovir

Study design

prospective cohort study

Intervention

treatment cessation.

Study burden and risks

the benefits include cessation of treatment without further need for taken a daily pill and also a reduction in potential long-term therapy associated risks, and a pronounced reduction in healthcare costs. Potential burdens and risks include additional follow-up visits and bloodwork during the period after therapy cessation. There appears to be a risk of severe hepatitis that carries a very low risk of subsequent liver failure if adequately treated.

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

Age 18 * 65 years
Treatment with entecavir or tenofovir
Previously HBeAg positive patients: stable HBeAg seroconversion (confirmed HBeAg seroconversion at least 6 months apart) with at least 12 months of subsequent consolidation therapy with HBV DNA <80 IU/mL
HBeAg negative patients: at least 3 years of continuous viral suppression (HBV DNA <80 IU/mL)
Fibroscan value <7.0 at baseline

Exclusion criteria

* History of liver biopsy with advanced fibrosis or cirrhosis (F3 or F4)
* History of hepatic decompensation
* (history of) hepatocellular carcinoma
* Other active malignancy
* (planned) treatment with immunosuppressive agents
* (planned) pregnancy
* Coinfection with HIV, HCV, HDV
* Concomitant liver condition that may influence liver chemistry (such as Gilbert*s syndrome). Defined as baseline ALT > 2x upper limit of normal, and/or bilirubin > 1x upper limit of normal.
* Other indication for continued nucleo(s)tide analogue therapy
* Expected noncompliance to follow-up
* Treatment with medication that increases INR (such as vitamin K antagonists)
* Unwillingness to refrain from sexual activity without condom with partners who are not vaccinated against hepatitis B virus

Study design

Design

Study phase: 4

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	27-11-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-04-2020
Application type:	Amendment
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	NL62412.078.17