SNAP study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27630

Source
Nationaal Trial Register

Brief title
SNAP study

Health condition

chronic hepatitis B

Sponsors and support

Primary sponsor: Erasmus MC

Intervention

Outcome measures

Primary outcome

Sustained response, defined as HBV DNA < 2,000 IU/mL at week 48 after therapy discontinuation.

Secondary outcome

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

2. HBsAg clearance at week 48. Occurrence of signs of liver failure (defined as bilirubin > 1.5

x the upper limit of normal and/or INR > 1.5)

4. Relationship between sustained response at week 48 and serum levels of HBsAg at the time of treatment cessation

Study description

Background summary

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Study objective

30-50% of patients will achieve sustained virological response after discontinuation of entecavir or tenofovir

Intervention

cessation of treatment

Contacts

Public
Milan Sonneveld
Rotterdam
The Netherlands
Scientific
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Rotterdam
The Netherlands

Eligibility criteria

Inclusion criteria

„X Age 18 ¡V 65 years

„X Treatment with entecavir or tenofovir

„X Previously HBeAg-positive patients: stable HBeAg seroconversion (confirmed HBeAg seroconversion at least 6 months apart) with at least 12 months of subsequent consolidation therapy

„X HBeAg negative patients: at least 3 years of viral suppression (HBV DNA <80 IU/mL).

Exclusion criteria

„X Presence of advanced liver disease defined as advanced fibrosis or cirrhosis (METAVIR F3 or F4; based on imaging, biopsy or liver stiffness assessment)

„X History of hepatic decompensation

„X (history of) hepatocellular carcinoma

„X Other active malignancy

„X (planned) treatment with immunosuppressive agents

„X (planned) pregnancy

„X Coinfection with HIV, HCV, HDV

„X Other indication for continued nucleo(s)tide analogue therapy

„X Expected noncompliance to follow-up

„X Unwillingness to refrain from sexual activity without condom with partners who are not vaccinated against hepatitis B virus

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-06-2017
Application type:	First submission

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
NTR-new	NL6814
NTR-old	NTR7001
Other	:

Study results

Summary results

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