Standardising care for hepatitis delta in the Netherlands

Published: 29-11-2023
Last updated: 28-04-2025

Generate prospective follow-up data to increase our understanding of this rare disease.

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

Summary

ID

NL-OMON56445

Source
ToetsingOnline

Brief title
DREAM-2

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
hepatitis D

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hepatitis Delta

Outcome measures

Primary outcome

Generate prospective population based follow-up data of a homogeneously managed hepatitis delta cohortGenerate prospective population based follow-up data of a homogeneously managed hepatitis delta cohort

Incidence of liver related events (liver cancer, (decompensation of) cirrhosis, liver transplantation) during follow-up and changes in markers of viral replication, inflammatory activity and liver stiffness over time.

Secondary outcome

Compare the outcomes of this cohort to a historic cohort identified in the DREAM-1 project

Study description

Background summary

Hepatitis delta virus (HDV) is a defective RNA virus that requires presence of hepatitis B virus (HBV) to complete virion assembly and secretion. HBV-HDV coinfection (*hepatitis delta*) has been associated with severe liver injury that may result in rapid progression to cirrhosis and hepatic decompensation, as well as a higher risk of liver cancer when compared to patients with HBV mono-infection. Given the low incidence of hepatitis D, experience in caring for individuals with hepatitis delta is limited and management practices vary.

Study objective

Generate prospective follow-up data to increase our understanding of this rare disease.

Study design

Prospective observational cohort study spanning 5 years, during which we will collect standard clinical data as well as blood samples and quality of life questionnaires.

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal. The only additional action that the participants must perform are the filling out of two annual quality of life questionnaires, which are considered non-invasive, and collection of 10 ml blood during regular blood sample collections.

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

- Active hepatitis delta based on a positive anti-HDV and a positive HDV-RNA test
- Patients must be >=18 years
- Written informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2024
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-11-2023
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2024
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	NL84655.078.23