An observational cross sectional cohort study to estimate the frequency of hepatitis E virus (HEV) infection in neurological disease of inflammatory/ immune mediated origin and ischemic stroke

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To estimate the frequency/ prevalence of acute or active HEV infection in patients presenting with (sub)acute post-infectious and/or immune-mediated neurological illness like neuralgic amyotrophy, (idiopathic) Guillain Barre syndrome, idiopathic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON42390

Source
ToetsingOnline

Brief title
Hepatitis E virus infection and neurological diseases

Condition

- Viral infectious disorders
- Peripheral neuropathies

Synonym
post infectious nervous system diseases, post-infectious neurological diseases

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: geen sponsoring

Intervention

Keyword: Hepatitis E virus, neurology, postinfectious

Outcome measures

Primary outcome

The number of HEV positive neurological patients (HEV PCR positive and/or IgM

positive.

Secondary outcome

To describe in detail the phenotypes of neurological illness of patients with a

recent HEV infection.

Study description

Background summary

Hepatitis E virus genotype 1 and 2 infections are hyperendemic in Africa and South-east Asia. The virus is transmitted via the fecal-oral route. Mortality is high in pregnant women. A recent study form Bangladesh concludes to a mortalty rate of 10%. The incidence of hepatitis E infections is increasing dramatically in Canada, USA, Europe, New Zealand and Japan. In the developed world HEV infection is caused by locally acquired genotype 3 which is a zoonotic with a porcine primary host in contrast to genotype 1 and 2 with a human host. Our understanding of the clinical range of HEV infection in humans has undergone a sea-change in recent years, and expands. There is a growing number of case-reports and case series with respect to the subject. Mainly neurological disorders like GBS, neuralgic amyotrophy, encephalitis, Bell*s palsy, transverse myelitis and peripheral neuropathies have been associated with HEV. In many case-reports of HEV-associated neurological injury the neurological symptoms and signs dominate the clinical picture and not the

hepatitis. Patients are usual anicteric and liverfunctions are only mildly to modestly abnormal. In routine clinical practice such patients are unlikely to be tested for HEV. Thus, the full range of HEV-associated neurological injury is unknown, and pathogenic mechanisms are uncertain.

Study objective

To estimate the frequency/ prevalence of acute or active HEV infection in patients presenting with (sub)acute post-infectious and/or immune-mediated neurological illness like neuralgic amyotrophy, (idiopathic) Guillain Barre syndrome, idiopathic facial nerve palsy (Bell*s palsy), vestibular neuritis, optic neuritis, transverse myelitis, non-infectious encephalitis, and patients with acute ischemic stroke.

Study design

This is an observational cohort pilot study of subjects over 18 years of age presenting at the Jeroen Bosch Hospital,*s-Hertogenbosch with (sub)acute post-infectious and/or immune-mediated neurological illness or acute ischemic stroke. If the patiënt gives informed consent an ELISA (Wantai, Beijing, PR China) will be performed to detect IgM and IgG antibodies to HEV. Additionally a validated quantative RT-PCR will be done.

Study burden and risks

Patients consent to give one blood sample (10 ml) in the far majority if not in all patients during an already planned venapunction. There is a very small chance of local hematoma due to venapunction without further risks.

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

Participant is willing and able to give informed consent for participation in the study.
Male or Female, aged 18 years or above.
Diagnosed with an (sub)acute post-infectious/ immune-mediated neurological disorder or ischemic stroke
Participants will have blood drawn for standard clinical care.

Exclusion criteria

-Not willing and able to give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	09-11-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL52981.028.15