

Seroprevalence of hepatitis E virus infections among vegetarians.

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|------------------------------|-----------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Gastrointestinal infections |
| Study type | Observational invasive |

Summary

ID

NL-OMON41208

Source

ToetsingOnline

Brief title

HEV seroprevalence among vegetarians.

Condition

- Gastrointestinal infections
- Hepatic and hepatobiliary disorders

Synonym

inflammation of the liver, viral hepatitis

Research involving

Human

Sponsors and support

Primary sponsor: GGD Amsterdam

Source(s) of monetary or material Support: Research & Development fonds GGD Amsterdam

Intervention

Keyword: Hepatitis E virus, Risk factors, Vegetarians

Outcome measures

Primary outcome

Primary outcome is the seroprevalence of HEV antibodies IgG en IgM in blood plasma

Risk factors for HEV antibodies will be assessed by using a structured questionnaire, focussing on consumption of meat/ (shell)fish.

Data and antibody status will be compared to available data of the control groups of the larger study.

Secondary outcome

Not applicable

Study description

Background summary

Hepatitis E virus (HEV) is a recently discovered virus that infects the liver and is transmitted via the fecal-oral route. An HEV infection is usually mild or without symptoms but it may infrequently lead to severe disease and complications, especially in chronically infected patients with immune-suppression, or in pregnant women.

Several countries in the world have endemic HEV transmission with a high seroprevalence (presence of IgG antibodies) to HEV. Epidemic outbreaks usually occur in these countries due to bad hygienic conditions and contaminated water. In Western countries sporadic cases are reported.

There is only one serotype but there are 4 genotypes of HEV which belongs to the genus Hepevirus. Genotypes 1 and 2 are so far strictly found in humans and mostly in endemic countries, whereas genotypes 3 and 4 are also found in animals such as pigs and wild boars, but also (shell)fish, in western countries. Since sequences of genotypes 3 and 4 are identical in animals and men it is speculated that HEV is a zoonosis for these types in western

countries such as the Netherlands.

Study objective

In the present study we aim to test the hypothesis that the reservoir of HEV in the Netherlands are animals that are bred for meat consumption. Therefore we want to compare the HEV seroprevalence in vegetarians and in people with a very low meat/ fish consumption with that of the general population (blood donors) and to that of a selected population of various ethnicities in Amsterdam (Helius study) and to immunocompromised persons, such as the HIV-infected persons from the Amsterdam Cohort studies. The control groups are not part of this study proposal..

Study design

In addition to collecting one (plasma)- blood sample we will also collect data on the participant using a structured questionnaire

Study burden and risks

Risk is minimal: drawing of one sample of blood might yield a bruise. Benefit for the individual participant is to provide data that might indicate that their lifestyle of a vegetarian diet protects against some infectious disease, in this case hepatitis E virus.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Male or female

18 years or older

Since 12 years of age or since last 10 years vegetarian, veganist, flexitarian

Written informed consent

Exclusion criteria

To consume more meat/ fish than once per week

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2014 |

| | |
|-------------|--------|
| Enrollment: | 400 |
| Type: | Actual |

Ethics review

| | |
|--------------------|--------------------|
| Approved WMO | |
| Date: | 29-09-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

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 | NL50095.018.14 |