

A descriptive study of the epidemiology and pathophysiology of hepatitis E infection in pregnant and non-pregnant women admitted to Patan Hospital, Kathmandu

Submission date 16/07/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 17/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/01/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nely Shrestha Khatri

Contact details
Patan Hospital
GPO BOX 252
Kathmandu
Nepal

-
+977 (0)1 984 128 9212
nelykhatri@gmail.com

Additional identifiers

Protocol serial number
ctu01hlmar08

Study information

Scientific Title

A prospective study of admitted women patients with hepatitis E to Patan Hospital

Study objectives

By identifying the cause for increased morbidity and mortality of hepatitis E virus (HEV) in pregnancy, we may be able to come up with reinforced strategies to prevent this disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Oxford Tropical Medicine Research Ethics Committee (OXTREC) (UK) on the 20th June 2008 (ref: 24/08). Ethics approval pending as of 16/07/2008 from the Nepalese local ethics committee.

Study design

A prospective descriptive epidemiology study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Hepatitis E virus

Interventions

Routine tests:

The following tests will be taken at baseline as this is routinely done at Patan Hospital:

1. Haematology: full blood count including white blood differential counts, reticulocytes, platelets. Further tests day 8 - 28 and 6 months or as clinically indicated.
2. Coagulation tests: prothrombin time/international normalised ratio (INR) on admission, then alternate days to daily accordingly
3. Blood culture at admission, further tests as clinically indicated
4. Biochemistry:
 - 4.1. Liver function tests: total bilirubin, direct bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase; measured weekly until they normalise
 - 4.2. Random blood glucose, as clinically indicated
 - 4.3. Creatinine, sodium/potassium; weekly or as clinically indicated
 - 4.4. Serology: hepatitis A immunoglobulins G and M (HepA IgG/M), hepatitis B surface antigen (HBsAg), anti-HBs and anti-core, hepatitis C IgG and hepatitis E IgG/M at admission
 - 4.5. Urine analysis
 - 4.6. Ultrasound; an abdominal ultrasound scan will be performed routinely for all patients to assess gestational age, liver texture, ascites, etc on admission and to obstetric demand

Tests for research study:

1. Viral polymerase chain reaction (PCR) for hepatitis A, B, C, D and E. EDTA blood sample on days 1, 2, 3, 7, 14, 28 and 6 months
2. Serology: hepatitis A IgG/M, HBsAg, anti-HBs and anti-core, hepatitis C IgG and hepatitis E IgG/M. Serology for toxoplasma, syphilis, typhoid, scrub typhus on days 1, 7, 14, 28 and 6 months

3. Immunology: EDTA blood for CD3, CD4, CD8, CD25 T cell counts on days 1, 7, 28 and 6 months
4. Ribonucleic acid (RNA) expression profiling: blood collection for the transcriptional profiling of cytokine levels and markers of immune activation/suppression on days 1, 7, 28 and 6 months (2 ml of blood needed) in the pregnant and non-pregnant patients

Subsidiary genetic study:

To understand why some patients become infected with HEV and why some patients develop fulminant hepatitis, an understanding of the genetic variation in the host is necessary. We can investigate the host genetic factors that are important in HEV infection by analysing deoxyribonucleic acid (DNA) (from 2 ml of blood) from 100 pregnant patients with symptoms of acute hepatitis and 100 non-pregnant patients with acute hepatitis. 2 ml of blood are necessary for this protocol.

Rectal swabs for viral PCR will be performed on admission and day 1, 2, 3, 7 and 14, 28 and 6 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Clinical, virological and immunological features of HEV infection in pregnant women in Patan Hospital will be studied, with particular reference to maternal and neonatal morbidity and mortality (in the pregnant patients only):

1. Mechanism of inducing high morbidity and mortality in pregnancy
2. Maternal death
3. The rate of preterm labour
4. Stillbirth
5. Intrauterine foetal death
6. Neonatal death
7. Post-partum haemorrhage
8. Rate of vertical transmission

Key secondary outcome(s)

We will be studying and recording the following outcomes in the pregnant and non-pregnant group:

1. Proportion of patients infected with HEV
2. Proportion of patients developing fulminant hepatitis in the two groups
3. Death
4. Correlation between viral loads, liver enzymes, liver activity scores, T-cell counts and clinical outcome
5. The route of infection in pregnant and non-pregnant women using GPS mapping and epidemiological data

Completion date

31/07/2011

Eligibility

Key inclusion criteria

1. All pregnant women aged greater than or equal to 15 years presenting to Patan Hospital with elevated liver enzymes and/or jaundice will be invited to participate in the study (100 patients)
2. All non-pregnant women aged greater than or equal to 15 years presenting to Patan Hospital with elevated liver enzymes and/or jaundice will be invited to participate in the study (100 patients)
3. Informed written consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. No consent
2. Other co-morbidities: chronic liver disease, chronic renal disease, cardiac disease
3. Alcohol abuse

Date of first enrolment

01/08/2008

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

Nepal

Study participating centre

Patan Hospital

Kathmandu

Nepal

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Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 077078)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration