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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

Registration date
17/07/2008

Last Edited
26/01/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Subsidary genetic study:
To understand why some patients become infected with HEV and why some patients develop fuminant 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 measure
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

Secondary outcome measures
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

Overall study start date
01/08/2008

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

Age group
Adult

Sex
Female

Target number of participants
Maximum of 100 patients

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)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
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England
United Kingdom
OX3 9DZ

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration