ISRCTN81497217 https://doi.org/10.1186/ISRCTN81497217

Investigation of the carriage of invasive Salmonellae in gall bladders in Kathmandu, Nepal

Submission date	Recruitment status	[X] Prospectively registered
16/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/07/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2008	Infections and Infestations	[_] 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
CTU02AVJUN08

Study information

Scientific Title

Study objectives
To understand why some people become chronic carriers of Salmonella we need to investigate the variation within the infecting pathogen and the host.

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 25th June 2008 (ref: 21/08). The Nepal Health Research Committee (NHRC) has given verbal approval and the written approval will follow.

Study design
A prospective descriptive study

Primary study design
Interventional

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
Enteric fever/tropical diseases

Interventions
1. Prior to admission to the study:
Full history and clinical examination. In particular the following data will be documented: clinical manifestations according to a standard case record form (CRF).

2. On admission to the study:
2.1. Name and address of the patient will be recorded on a detachable cover sheet of the CRF
2.2. Blood for on-going host genetic studies of enteric fever from the patient
2.3. Storage of serum for antibody analysis
2.4. Storage of blood for expression microarray profiling to identify biomarkers of carriage
2.5. Storage of bile and gallbladder

2.6. Culture of bile and gall stones (if present)
2.7. Stool culture

3. Follow up visit from health-workers after 3 months:
3.1. Stool culture
3.2. GPS mapping of patients house
3.3. The gallbladders and bile will be stored in appropriate media and temperatures for:
3.3.1. Polymerase chain reaction (PCR) of Salmonella deoxyribonucleic acid (DNA) in all samples that are culture negative
3.3.2. Bacterial ribonucleic acid (RNA) extraction for expression profiling of the organism
3.3.3. Routine histology of the organ
3.3.4. Immunohistochemistry of the tissue
3.3.5. Electron microscopy of the tissue
3.4. Blood and serum will be stored in appropriate media and temperatures for:
3.4.1. Storage of blood for expression microarray profiling to identify biomarkers of carriage
3.4.2. Blood for on-going host genetic studies of enteric fever from the patient
3.4.3. Storage of serum for antibody analysis
3.5. Storage of bacterial isolates; all strains isolated from the bile will be stored at -700°C for bacteriological assessment
3.6. Spatial clustering of typhoid fever cases

Patients will be visited twice daily at home by a member of the study team. At the first visit the staff member will record the patient's house in a global positioning system (GPS).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The titre of Vi antibodies in patients from whom Salmonella is isolated
2. Specific histological characteristics favouring carriage of Salmonella
3. Traits of the bacterium favouring their chronic carriage

Secondary outcome measures
1. Investigation of the host genetic variation
2. The human expression profile involved with Salmonella carriage

Overall study start date
01/08/2008

Completion date
31/07/2011

Eligibility

Key inclusion criteria
All patients referred for Cholecystectomy at Patan Hospital (no age limit, either sex) that complete the consent form and agree to be admitted to the study will be included in the study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
1000

Key exclusion criteria
Does not comply with the above inclusion criteria.

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
-

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford

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