

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

<b>Submission date</b> 16/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/07/2008	<b>Condition category</b> 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

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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

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**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