

Enhancing dermatological diagnoses in patients with skin diseases at the National Institute for Infectious and Tropical Diseases in Hanoi

Submission date 16/07/2008	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 17/07/2008	Overall study status Completed	☐ Protocol
Last Edited 16/10/2008	Condition category Skin and Connective Tissue Diseases	☐ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

ctu01dtfec08

Study information

Scientific Title

Study objectives

The rationale of this protocol is to begin the first steps of skin research at National Institute for Infectious and Tropical Diseases in Hanoi.

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: 12/08). Ethics approval pending as of 16/07/2008 from the ethics committee of the National Institute of Infectious and Tropical Diseases (NIITD).

Primary study design

Interventional

Study design

This is a pilot study without a formal sample size calculation.

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Dermatology/skin rashes

Interventions

This pilot study is not randomised or controlled. Potential study participants will be patients with a rash of unknown cause or with a suspected rash of one of the diseases of interest. For the patients in whom a skin biopsy is thought to be clinically important, a discussion will first take place between the research team and the treating physicians. If it is decided that a skin biopsy is indicated, the patient will be told about the study and, if interested, a member of the research team will go through the informed consent process.

Skin biopsies will be divided and placed in suitable media for further investigation. This will include:

1. 10% buffered formalin for routine histology and polymerase chain reaction (PCR)
2. Michel's solution for immunofluorescence
3. Viral transport medium for viral culture
4. Sterile container for bacterial or fungal culture
5. Glutaldehyde for electron microscopy

If a skin scraping is done, it will be sent for microscopy (KOH stain) and/or fungal culture. Fluid from vesicles may be sent to the laboratory for herpes PCR. Basic clinical history, past medical history, drug history, previous skin diseases, physical examination, including the skin rash distribution, and the results of routine investigations will also be performed.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical diagnosis

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. Patients admitted to the NIITD of any age, either sex
2. Obtaining informed consent
3. Any patient with an undiagnosed rash
4. Any patient with suspected *Streptococcus suis*, *Penicillium marneffei*, typhus or dengue

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

An active bleeding tendency

Date of first enrolment

31/07/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Viet Nam

Study participating centre

The Oxford University Clinical Research Unit (OUCRU)

Hanoi

Viet Nam

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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