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

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
16/10/2008	Skin and Connective Tissue Diseases	[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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).

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Dermatology/skin rashes

Interventions
This pilot study is not randomised or controlled. Potential study participants will be patients with a rash of unknown cause of 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 immunoflourescence
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 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 measure
Clinical diagnosis

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/07/2008

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

Age group
Not Specified

Sex
Both

Target number of participants
100 patients

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)

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