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A double blind study of dexamethasone for the treatment of H5N1 Avian Influenza

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/12/2007	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
061330

Study information

Scientific Title

Acronym
DL Study

Study objectives
We have started to see new cases of H5N1 infection. Five new cases confirmed in the last week all from different provinces of southern Viet Nam suggesting widespread (and therefore difficult to control) distribution of the virus. We suspect that this epidemic will prove more extensive than 2004. There is more than 80% mortality in the confirmed cases and most severe cases have been in children and teenagers. All patients are managed in a dedicated ward with barrier nursing and medical care. All patients are treated with oseltamivir for five days. Some patients have been given steroids some have not. There is no evidence on which to guide treatment, drugs, doses or duration. We have documented massive cytokine release in the patients from 2004. Our TaqMan real time Polymerase Chain Reaction (PCR) results are available within 24 hours of a sample being taken.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Avian Influenza

Interventions
Dexamethasone

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome measure
Mortality

Secondary outcome measures
1. Duration of ventilation
2. Duration of supplemental oxygen
3. Duration of hospitalisation
4. Viral load in clinical specimens
5. Cytokine levels
6. Adverse effects

Overall study start date
01/01/2005

Completion date
31/12/2006

Reason abandoned (if study stopped)
No patients with H5N1 in Viet Nam since August 2005, only four patients recruited in total. Data being analysed.

Eligibility

Key inclusion criteria
1. Patients with confirmed TaqMan Influenza A positive, or H5N1 PCR
2. Patients with history of clear close exposure to sick poultry, Chest X-Ray changes consistent with H5N1, low white count and strong clinical suspicion of H5N1 infection

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
4 - recruitment terminated as not enough patients

Key exclusion criteria
No consent

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Viet Nam

Study participating centre
Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

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: 061330)

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