

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

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| Submission date 22/07/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 22/07/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 13/12/2007 | Condition category 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Mortality

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR
<https://ror.org/052gg0110>

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 061330)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration