

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

|                          |                             |                                                      |
|--------------------------|-----------------------------|------------------------------------------------------|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input type="checkbox"/> Prospectively registered    |
| 22/07/2005               | No longer recruiting        | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan   |
| 22/07/2005               | Completed                   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> Individual participant data |
| 13/12/2007               | Infections and Infestations | <input type="checkbox"/> 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

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