Avian/Pandemic Influenza Registry (AVEX Registry)

First published: 12/08/2011

Last updated: 31/07/2012

Study Finalised

Administrative details

EU PAS number

EUPAS2113

Study ID

2865

DARWIN EU® study

No

Study countries

- Azerbaijan
- Bangladesh
- Cambodia
- China
- Egypt
- Hong Kong

Indonesia
Lao People's Democratic Republic
Nigeria
Pakistan
Thailand
Türkiye
Viet Nam

Study description

This is an observational patient registry of humans infected with avian influenza A (H5N1). The registry is a collaborative study involving members of the international scientific, medical and public health communities. The registry collects information from many countries on patients' exposures, symptoms, presentation for medical care, virologic testing, treatment, clinical course and survival in order to better understand the clinical course and effectiveness of current treatments for H5N1 infections in humans.

Study status

Finalised

Research institutions and networks

Institutions

Scientific Affairs, Outcome SARL

Switzerland

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Institution | Other

Multiple centres: 9 centres involved in this study across 9 countries, list available on request

Networks

Full list available on request

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nancy Dreyer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2007

Actual: 12/12/2006

Study start date
Planned: 03/04/2007

Actual: 26/03/2007

Data analysis start date
Planned: 16/10/2007

Actual: 16/10/2007

Date of interim report, if expected
Planned: 15/07/2011

Actual: 18/07/2011

Date of final study report
Planned: 30/06/2012

Actual: 20/06/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Study protocol

Avian-Pandemic Influenza Registry_Revised Protocol_16Oct08Final.pdf (119.72 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To better understand the clinical course of infection with H5N1, and the effectiveness of curently treatments used in humans

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Medical condition to be studied

Avian influenza

Population studied

Short description of the study population

All patients who developed influenza-like symptoms and who are considered to be epidemiologically linked by time, place, and exposure to a probable or confirmed avian influenza or human pandemic influenza case (in poultry, wild birds, animals or humans). In addition, patients with documented seroconversion (positive serological test in a national, regional or international influenza laboratory whose test results confirm infection with avian influenza), who either remain asymptomatic or experience only mild illness will be eligible for inclusion. All cases identified in the literature, by treating physicians and other health care providers or by local government or international agencies will be pursued for inclusion in the registry.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients infected with avian influenza A (H5N1)

Estimated number of subjects

647

Study design details

Outcomes

survival, discharge from hospital with serious impairments

Data analysis plan

Analyses are primarily descriptive. Relative risks are used to compare survival in patients receiving antivirals and other treatments compared to those who did not receive those treatments, and to understand the impact of various effect modifiers and potential confounders. Multivariate modeling may be used to examine the relationship between survival and a variety of clinical and epidemiologic factors. Multiple imputation may be used for important missing data.

Documents

Study publications

Adisasmito W, Chan PK, Lee N, Oner AF, Gasimov V, Aghayev F, Zaman M, Bamgboye …

Oner AF, Dogan N, Gasimov V, Adisasmito W, Coker R, Chan PK, Lee N, Tsang O, Ha…

Chan PK, Lee N, Zaman M, Adisasmito W, Coker R, Hanshaoworakul W, Gasimov V, On…

Zaman M, Ashraf S, Dreyer NA, Toovey S. Human infection with avian influenza vi…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Medical record review; published case studies with detailed patient data; case data from national public health

agencies

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No