

Effect of clarithromycin on influenza infection

Submission date 25/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Influenza viruses cause substantial disease burden every year. Patients are frequently hospitalised for pneumonia secondary to influenza infection. Clarithromycin and naproxen inhibit seasonal influenza virus infection in human airway epithelial cells with additional anti-inflammatory effects. The aim in this study is to assess the effects of clarithromycin and naproxen in patients diagnosed with pneumonia secondary to respiratory viral infection.

Who can participate?

Adult patients, hospitalised in Queen Mary Hospital, Hong Kong (China) for pneumonia

What does the study involve?

Patients will be randomly assigned to a 5-day course of amoxicillin-clavulanate and oseltamivir and a 2-day course of double combination of naproxen and clarithromycin (study arm) or a 5-day course of amoxicillin-clavulanate and oseltamivir (control group).

What are the possible benefits and risks of participating?

Possible benefits include reduction in mortality, shortened hospital stay, faster fever resolution and viral load reduction. Risks not provided at time of registration

Where is the study run from?

Queen Mary Hospital, Hong Kong (China)

When is the study starting and how long is it expected to run for?

February 2015 to April 2016

Who is funding the study?

University of Hong Kong (China)

Who is the main contact?

Dr Ivan Hung
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

UW 14-540

Study information

Scientific Title

Effect of clarithromycin on influenza respiratory tract infection: an open-label randomised controlled trial

Study objectives

A combination of clarithromycin, oseltamivir and naproxen will expedite the recovery, suppress the viral load, shorten hospitalisation and reduce mortality in patients with influenza respiratory tract infection compared with oseltamivir alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Hong Kong/Hospital Authority Hong Kong West Cluster Institutional Review Board, 05/11/2014, UW 14-540

Study design

Open-label randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Influenza, lower respiratory tract infection

Interventions

Current interventions as of 16/02/2015:

Study arm: 5-day course of amoxicillin-clavulanate + oseltamivir and a 2-day course of double combination of naproxen and clarithromycin

Control arm: 5-day course of amoxicillin-clavulanate + oseltamivir

Previous interventions:

1. Study arm: 2-day course of oseltamivir + clarithromycin + naproxen + 7-day course of amoxicillin-clavulanate

2. Control arm: 2-day course of oseltamivir + 7-day course of amoxicillin-clavulanate

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

1. Oseltamivir 2. Clarithromycin 3. Naproxen 4. Amoxicillin-clavulanate

Primary outcome measure

Current primary outcome measures as of 13/07/2018:

30-day mortality

Previous primary outcome measures:

Nasopharyngeal aspirate viral load reduction, measured with polymerase chain reaction from day 0 (baseline) to day 3 after recruitment

Secondary outcome measures

Current secondary outcome measures as of 13/07/2018:

1. 90-day mortality

2. Serial changes in the nasopharyngeal aspirate (NPA) virus titer
3. Percentage change of neuraminidase-inhibitor-resistant A(H3N2) virus (NIRV) quasispecies measured by means of pyrosequencing
4. Pneumonia severity index (PSI) from days 1 to 4 after antiviral treatment
5. Length of hospitalisation

Previous secondary outcome measures:

1. Resolution of fever (from day 0 to day 3)
2. Duration of hospitalisation (from admission to discharge from hospital for that particular admission)
3. Mortality rate (from day of recruitment to 1 month after recruitment)

Overall study start date

04/02/2015

Completion date

30/04/2016

Eligibility

Key inclusion criteria

1. Age \geq 18 years
2. Diagnosed of influenza, lower respiratory tract infection
3. Requiring hospitalisation
4. Willing to comply with the study programme
5. Provided informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Allergic to clarithromycin, amoxicillin-clavulanate, oseltamivir, or naproxen
2. Moderate renal impairment (creatinine clearance < 30 mL/min)
3. Pregnancy
4. Breastfeeding
5. Inability to comprehend and follow all required study procedures
6. Human immunodeficiency virus (HIV) infection
7. Received an experimental agent (vaccine, drug, biological, device, blood product or

medication) within 1 month before recruitment or expecting to receive an experimental agent during the study

8. Unwillingness or refusal to participate in another clinical study after the end of this study

9. History of alcohol or drug abuse in the past 5 years

10. Any condition that the investigator believes might interfere with successful completion of the study

Date of first enrolment

18/02/2015

Date of final enrolment

30/04/2015

Locations

Countries of recruitment

China

Hong Kong

Study participating centre

Queen Mary Hospital

102 Pokfulam Road

Hong Kong

China

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Sponsor information

Organisation

University of Hong Kong

Sponsor details

Medical School

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Sponsor type

University/education

ROR

https://ror.org/02zhqgq86

Funder(s)

Funder type

University/education

Funder Name

University of Hong Kong

Alternative Name(s)

The University of Hong Kong, , Universitas Hongkongensis, HKU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Hong Kong

Results and Publications

Publication and dissemination plan

To publish in an infectious diseases journal

Intention to publish date

31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017	17/12/2020	Yes	No