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Effect of clarithromycin on influenza infection

Submission date	Recruitment status	[X] Prospectively registered
25/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2020	Infections and Infestations	

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

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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 ≥ 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

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University of Hong Kong

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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