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Respiratory illness in people living with HIV in the era of antiretroviral therapy

Submission date
21/04/2017

Recruitment status
No longer recruiting

Registration date
27/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
The human immunodeficiency virus (HIV) is a type of virus known as a retrovirus. HIV attacks and weakens the immune system, making it more difficult for a sufferer to fight infections. It is a highly contagious disease, through bodily fluids such as blood, semen and vaginal fluids. There is currently no cure for HIV, but there are a range of drug treatments (antiretroviral therapy) that can help people who are HIV positive to lead a long and full life. HIV infection is associated with a high rate of respiratory (breathing) disease despite the use of antiretroviral therapy. As the HIV positive population in the UK ages, long-term lung diseases such as COPD will become increasingly important. A better understanding of the causes of respiratory illness in this population is therefore needed to help find ways to reduce the impact of disease. The aim of this study is to look at the frequency of acute respiratory illness (a sudden illness that affects breathing) in those with HIV who have access to antiretroviral therapy compared to people without HIV.

Who can participate?
Adults who are HIV positive and those who are HIV negative.

What does the study involve?
All participants are followed for a period of 12 months. During this time they are asked to complete weekly diaries to assess the development of any acute respiratory illness. When such illnesses occur, participants are asked to attend for review - at these times the severity and duration of these acute respiratory illnesses are measured using breathing tests, blood tests, and questionnaires. In addition, samples are taken from the nose and throat using nasal swabs and lungs which are analysed to find out what has caused the condition in the laboratory.

What are the possible benefits and risks of participating?
Participants benefit from receiving the results of their lung function tests, which can also be passed onto their GP. This could help their future care. During the study participants are asked to contact one of the research team if they get any new respiratory symptoms such as coughing, blocked or runny nose, breathlessness or chest pain. If this happens the researchers will then arrange to see the participants again and to take samples. If any micro-organisms that are causing infection are identified at these times then this might help with treatment. There are no

significant risks anticipated. The swabs taken from participant's noses and throats and blood testing may cause mild discomfort. In a few cases collecting samples from the chest may cause wheezing.

Where is the study run from?
Royal Free Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to February 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr James Brown
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Contact information

Type(s)
Public

Contact name
Dr James Brown

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RFL9065

Study information

Scientific Title
Acute respiratory tract illness in an HIV infected population with a high uptake of antiretroviral therapy

Study objectives
Research questin:
Do HIV positive individuals have a higher frequency of acute respiratory illness in a setting with good access to effective antiretroviral therapy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Hampstead, 15/09/2014, ref: 14/LO/1409

Study design
Prospective observational epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Acute respiratory illness

Interventions
All participants will have baseline tests and then be asked to report the frequency of acute respiratory illness over a 12 month period. When participants develop an acute respiratory illness, they will be asked to complete a diary recording the severity and duration of this illness and attend to have samples taken for microbiological analysis.

Intervention Type
Other

Primary outcome measure
The annual incidence of acute respiratory illness in HIV positive compared to HIV negative participants is measured over 12 months of follow-up with weekly contacts to participants.

Secondary outcome measures

1. Duration of symptoms during respiratory tract illness in HIV infected and uninfected participants is measured by participant diaries completed daily during acute respiratory illness
2. Health-related quality of life measured by the St Georges Respiratory Questionnaire and EuroQoL-5D at baseline
3. Healthcare resource utilisation arising from acute respiratory illness during acute respiratory tract illness measured using participant daily diaries
4. The prevalence of positive microbial isolation in throat swabs and sputum samples at baseline
5. The prevalence of positive microbial isolation during acute respiratory illness in throat swabs and sputum samples
6. The baseline prevalence of obstructive lung disease is measured by pre-bronchodilator spirometry at baseline

Overall study start date
15/09/2014

Completion date
01/02/2018

Eligibility

Key inclusion criteria
HIV-infected cohort:
1. HIV positive
2. Willing to participate in study and able to return for review in the event of respiratory tract infections, and to participate for the duration of the study
3. 18 years or above

HIV-uninfected participants:
1. Willing to participate in study and able to return for review in the event of respiratory tract infections, and to participate for the duration of the study
2. 18 years or above
3. Consent to HIV testing
4. Negative HIV test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Total final enrolment

Key exclusion criteria
1. Unable to participate for the full duration of the study
2. Unable to return for review in the event of respiratory tract infection (for instance those living a long distance from the study site)
3. Current significant acute respiratory tract illness such as pulmonary tuberculosis, Pneumocystis jirovecii pneumonia

Date of first enrolment
01/12/2015

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
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WC1E 6BT

Sponsor type
University/education

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in an open-access peer reviewed journal within 12 months of study completion.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to existing research ethics permissions regarding data storage.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.2	04/08/2014	27/04/2017	No	Yes
Participant information sheet	version V1	17/06/2014	27/04/2017	No	Yes
	results				

Results article	29/05/2020	01/06/2020	Yes	No
Dataset	13/05/2020	07/06/2023	No	No
Other publications	25/02/2021	07/06/2023	Yes	No
Other publications	27/06/2020	07/06/2023	Yes	No
HRA research summary		28/06/2023	No	No