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Pharmacogenetics of human immunodeficiency virus therapy

Submission date	Recruitment status	[_] Prospectively registered
28/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7342

Study information

Scientific Title
Host genetic factors influencing drug disposition and response to human immunodeficiency virus treatment

Study objectives
This is a study to investigate the association between genetic polymorphisms and:
1. Treatment response (viral load and CD4 count), or
2. Drug exposure in human immunodeficiency virus (HIV) positive patients

The cohort study examines treatment response after starting or switching antiretroviral therapy (ART) regimen according to genotype. There is also a cross-sectional study where the primary endpoint is the measured concentration of antiviral drug. The relationship between drug exposure and genetic polymorphism will also be examined.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=7342

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West MREC (now changed to North West 5 Research Ethics Committee), 07/11/2003, ref: 02/8/87

Study design
Multicentre non-randomised observational treatment cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions

Study A:
This study is examining treatment response after starting or switching antiretroviral therapy according to genotype with the primary endpoint of a change in CD4 count and viral load at 24 weeks.

Study B:
This study involves obtaining a single blood sample in which drug concentrations will be measured. The primary endpoint is the measurement of the antiretroviral drug.

Genomic DNA will be purified and quantified from both studies. Genetic polymorphisms will be defined by PCR-RFLP, sequence-specific PCR or SNaPshot as optimised for each allele to be examined.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Change in CD4 count and viral load, measured at 24 weeks, with secondary endpoints of viral load at 12 weeks and time to/proportion achieving undetectable viral load

Secondary outcome measures
1. Change in viral load at 12 weeks
2. Time to/proportion achieving undetectable viral load

Overall study start date
24/04/2007

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Study A:
Recruitment from existing cohort studies

Study B:
1. Aged greater than 18 years
2. Know HIV-seropositive
3. Receiving antiretroviral therapy
4. Having drug concentration measured

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 900

Key exclusion criteria
Study A:
Recruitment from existing cohort studies

Study B:
1. Aged less than 18 years
2. Not on antiretroviral therapy

Date of first enrolment
24/04/2007

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool Hospital
Liverpool
United Kingdom
L69 3GA

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
Thompson Yates Building
Quadrangle Brownlow Hill
Liverpool

England
United Kingdom
L69 3GB
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research@rlbuht.nhs.uk

Sponsor type
University/education

Website
http://www.liv.ac.uk/

Organisation
Royal Liverpool and Broadgreen University Hospitals NHS Trust (UK)

Sponsor details
Prescot Street
Liverpool
England
United Kingdom
L7 8XP

Sponsor type
Hospital/treatment centre

Organisation
University of Liverpool

Sponsor details

Sponsor type
Not defined

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008	21/01/2019	Yes	No
Results article	results	01/02/2014	21/01/2019	Yes	No
Results article	results	01/05/2009	21/01/2019	Yes	No
Results article	results of population pharmacokinetic modeling of the association between 63396C->T pregnane X receptor polymorphism and unboosted atazanavir clearance	01/12/2010	21/01/2019	Yes	No
Results article	results of the association of ABCC10 polymorphisms with nevirapine plasma concentrations	01/01/2012	21/01/2019	Yes	No
Results article	results of the effect of SLCO1B1 polymorphisms on lopinavir plasma concentration in HIV-infected adults	01/02/2012	21/01/2019	Yes	No
Results article	results of the effects of SNPs within OATP1A2, OATP1B1 and OATP1B3 on the pharmacokinetics of lopinavir	01/02/2010	21/01/2019	Yes	No