

# Pharmacogenetics of human immunodeficiency virus therapy

<b>Submission date</b> 28/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

**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**

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Quadrangle Brownlow Hill

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**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?
<a href="#">Results article</a>	results	01/11/2008	21/01/2019	Yes	No
<a href="#">Results article</a>	results	01/02/2014	21/01/2019	Yes	No
<a href="#">Results article</a>	results	01/05/2009	21/01/2019	Yes	No
<a href="#">Results article</a>	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
<a href="#">Results article</a>	results of the association of ABCC10 polymorphisms with nevirapine plasma concentrations	01/01/2012	21/01/2019	Yes	No
<a href="#">Results article</a>	results of the effect of SLCO1B1 polymorphisms on lopinavir plasma concentration in HIV-infected adults	01/02/2012	21/01/2019	Yes	No
<a href="#">Results article</a>	results of the effects of SNPs within OATP1A2, OATP1B1 and OATP1B3 on the pharmacokinetics of lopinavir	01/02/2010	21/01/2019	Yes	No