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The Liverpool human immunodeficiency virus (HIV) therapeutic drug monitoring (TDM) registry

Submission date	Recruitment status	[_] Prospectively registered
16/04/2008	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2008	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2021	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Human immunodeficiency virus (HIV) attacks the immune system and weakens the body's ability to fight infections. It can be treated with drugs that stop the virus from replicating. The aim of this study is to determine the effects of various factors on the pharmacokinetics of HIV drugs. Pharmacokinetics refers to what the body does to a drug as it moves into, through and out of the body.

Who can participate?
HIV-infected patients

What does the study involve?
Data is collected about patients in order to analyse the effect of age, weight, gender and interacting medications on the concentrations of HIV drugs in plasma (blood) samples. In addition, DNA is extracted from these plasma samples and analysed.

What are the possible benefits and risks of participating?
It is hoped that this study may help us understand why treatment response and drug levels vary in HIV patients. The data will be anonymised so that individual patients cannot be traced.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
October 2005 to January 2030

Who is funding the study?
British Society for Antimicrobial Chemotherapy (BSAC) (UK)

Who is the main contact?
Dr Saye Khoo
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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
Version 2.1

Study information

Scientific Title
The Liverpool human immunodeficiency virus (HIV) therapeutic drug monitoring (TDM) registry: studying influences upon plasma human immunodeficiency virus drug exposure

Study objectives
Human immunodeficiency virus (HIV) therapeutic drug monitoring (TDM) registry studying the effects of gender, body weight, age, ethnicity, interacting medication and host genetics upon pharmacokinetics of HIV drugs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics approval received from the North West Multi-Regional Ethics Committee, 03/10/2005, ref: 05/MRE08/67

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus

Interventions
The TDM registry is a registry of patients in whom therapeutic drug monitoring has been requested for HIV drugs. Data are kept anonymised, but linked to date of birth and hospital number.

The TDM registry seeks to collate all data from patients undergoing TDM in order to analyse the effect of co-variates (age, weight, gender, concomitant medications, etc.) on concentrations of HIV drugs in plasma. In addition, DNA will be extracted from these plasma samples after second round of irreversible anonymisation, in which data relating to date of birth and hospital unit number are permanently removed so that individual patients cannot be traced. It is hoped that the ability to understand both the pharmacogenetic and the environmental influences upon HIV drug exposure may contribute to our understanding of why treatment response and drug levels are variable in HIV+ patients, particularly with respect to gender, ethnicity and host genetic influences.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Correlation between drug exposure and:
1. Age, gender, weight, disease status, interacting medications, pregnancy etc.
2. Host genomic profile (genes implicated in HIV disease process and drug disposition)

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/10/2005

Completion date
01/01/2030

Eligibility

Key inclusion criteria
Request for TDM of HIV drugs

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
TDM requests greater than 10,000 and approximately 4000 archived plasma samples

Key exclusion criteria
Nil. Separate filters will be applied when analysing data, e.g. for children, pregnant women, patients on dialysis, patients receiving chemotherapy etc.

Date of first enrolment
01/10/2005

Date of final enrolment
01/01/2030

Locations

Countries of recruitment
England

Ireland

Israel

United Kingdom

Study participating centre
University of Liverpool
Liverpool

United Kingdom
L69 3GF

Sponsor information

Organisation
University of Liverpool

Sponsor details
Research & Business Service
The Foresight Centre
3 Brownlow Street
Liverpool
England
United Kingdom
L69 3GL

Sponsor type
University/education

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

ROR
https://ror.org/04xs57h96

Organisation
Royal Liverpool and Broadgreen University Hospital NHS Trust

Sponsor details
Prescot Street
Liverpool
England
United Kingdom
L7 8XP

Sponsor type
Hospital/treatment centre

Website
http://www.rlbuht.nhs.uk/

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Research organisation

Funder Name
British Society for Antimicrobial Chemotherapy - Academic Initiative Grant (ref: PG/A1-05)

Alternative Name(s)
BSAC

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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	01/12/2008		Yes	No
Results article	results	01/05/2009		Yes	No
Results article	results	01/06/2009		Yes	No
Results article	results	01/08/2009		Yes	No
Results article	results	01/01/2010		Yes	No
Results article	results	01/02/2010		Yes	No

Results article	results	01/12/2010	Yes	No
Results article	results	01/01/2011	Yes	No
Results article	results	01/03/2011	Yes	No
Results article	results	01/06/2011	Yes	No
Results article	results	01/06/2011	Yes	No