

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

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

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

khoo@liv.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Saye Khoo

Contact details

University of Liverpool

Department of Pharmacology & Therapeutics

1st Floor, The Infirmary

70 Pembroke Place

Liverpool

United Kingdom

L69 3GF

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khoo@liv.ac.uk

Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Observational case-control study

Study type(s)

Screening

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-variables (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(s)

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)

Key secondary outcome(s)

No secondary outcome measures.

Completion date

01/01/2030

Eligibility**Key inclusion criteria**

Request for TDM of HIV drugs

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

England

Ireland

Israel

Study participating centre

University of Liverpool

Liverpool

United Kingdom

L69 3GF

Sponsor information

Organisation

University of Liverpool

ROR

<https://ror.org/04xs57h96>

Organisation

Royal Liverpool and Broadgreen University Hospital NHS Trust

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

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