Clinical trial results:
The Liverpool HIV TDM Registry: Studying influences upon plasma HIV drug exposure

Summary

EudraCT number	2006-006076-38
Trial protocol	GB
Global end of trial date	30 December 2015

Results information

Result version number	v1 (current)
This version publication date	25 March 2022
First version publication date	25 March 2022
Summary attachment (see zip file)	TDM registry report (3173 TDM Registry End of study report.pdf)

Trial information

Trial identification

Sponsor protocol code	RLBUHT3173

Additional study identifiers

ISRCTN number	ISRCTN65117827
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Sponsor: UoL000071

Notes:

Sponsors

Sponsor organisation name	Royal Liverpool & Broadgreen University Hospitals NHS Trust
Sponsor organisation address	Prescot Street, Liverpool, United Kingdom, L7 8XP
Public contact	Heather Rogers, Royal Liverpool & Broadgreen University Hospitals NHS Trust, 0151 7062000, rgt@rlbuht.nhs.uk
Scientific contact	Prof Saye Khoo, University of Liverpool, 0151 7945560, khoo@liv.ac.uk
Sponsor organisation name	University of Liverpool
Sponsor organisation address	3 Brownlow Street, Liverpool, United Kingdom, L69
Public contact	Karen Wilding, University of Liverpool, 0151 7942000, sponsor@liverpool.ac.uk
Scientific contact	Prof Saye Khoo, University of Liverpool, 0151 7945560, khoo@liv.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 December 2015
Global end of trial reached?	Yes
Global end of trial date	30 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the association between genetic polymorphisms and a) treatment response (viral load and CD4 count), or b) drug exposure in HIV+ patients.

A candidate gene approach will be utilised to examine the following loci of interest:
Drug metabolism e.g. CYP P450- 2C9, 2D6 and 2C19
Drug transporters e.g. MDR1 (P-gp), MRP-1, MRP-2, MRP-5
Protein binding e.g. ORM1

Other candidate genes will emerge as genetic polymorphisms are characterised - these include other drug transporter and metabolising enzymes, and their effect on drug efficacy as well as drug toxicity.

Protection of trial subjects:

This study used samples only from irreversibly anonymised participants. No trial participants were recruited or exposed to IMP.

Background therapy:

HIV antiretroviral therapy

Evidence for comparator: -

Actual start date of recruitment	26 April 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No participant recruitment took place for this registry. Ethics approval received to extract DNA samples from samples following second round of anonymisation.

Pre-assignment

Screening details:

Samples in the registry that were known to be from patients receiving HIV antiretrovirals were available for inclusion in this study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Overall trial
Arm description: -	
Arm type	Sample analysis
Investigational medicinal product name	No IMP administered
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Other use

Dosage and administration details:

No IMP was administered in this study.

Number of subjects in period 1	Overall trial
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall trial

Reporting group description: -

Primary: Drug concentrations

End point title	Drug concentrations[1]

End point description:

0 participants were recruited in this trial. Samples were analysed from the TDM Registry.

End point type	Primary

End point timeframe:

Random samples

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: See attached document for statistical analysis

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: ng.mL				
number (not applicable)	99999			

Notes:

[2] - Analysis on samples, no patients recruited

Attachments (see zip file)	Statistical analysis.docx

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse event reporting was confined to the participation in the therapeutic drug monitoring process. No drug exposure occurred in this study.

Assessment type	Systematic

Dictionary used

Dictionary name	DAIDS
Dictionary version	2.0

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No subjects were enrolled in the trials hence no safety data are available. No intervention was given. This was a study on samples in a registry.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 November 2006	Protocol updated to include adverse event reporting in response to the MHRA opinion that the trial qualified as a CTIMP
02 May 2007	Substantial amendment to change the trial to a CTIMP following review by the MHRA

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

There were no participants recruited to this study. Irreversibly anonymised samples were used for the study.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/24950369

http://www.ncbi.nlm.nih.gov/pubmed/22477766

http://www.ncbi.nlm.nih.gov/pubmed/23435690

http://www.ncbi.nlm.nih.gov/pubmed/20051929

http://www.ncbi.nlm.nih.gov/pubmed/20921307

http://www.ncbi.nlm.nih.gov/pubmed/19897506

http://www.ncbi.nlm.nih.gov/pubmed/18831695

http://www.ncbi.nlm.nih.gov/pubmed/18771051