

# Children with HIV in Africa - Pharmacokinetics and Adherence of Simple Antiretroviral Regimens (CHAPAS-2)

<b>Submission date</b> 28/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/04/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

Children with HIV in Africa - Pharmacokinetics and Adherence of Simple Antiretroviral Regimens (CHAPAS-2): an open, randomised, controlled, phase I, crossover trial

## Acronym

CHAPAS-2

## Study objectives

1. There is no difference in blood drug levels (overall area under the plasma concentration time curve (AUC) and Cmin) among children aged 4-13 years taking Cipla sprinkle or Cipla tablet formulations of ritonavir-boosted-lopinavir together with food and also compared to historical controls.
2. There is no difference in blood drug levels (overall area under the plasma concentration time curve (AUC) and Cmin) among infants (under 1 year) taking Abbott Kaletra® syrup or Cipla sprinkle formulations of ritonavir-boosted-lopinavir together with food according to World Health Organisation (WHO) doses and weightbands and also compared to historical controls.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. UCL Research Ethics Committee approved on 19th October 2009, (ref: application 1665/001)
2. Joint Clinical Research Centre IRB approved on 30th October 2009
3. Ugandan National Council of Science and Technology approved on 23rd April 2010

## Study design

Open randomised controlled phase I crossover trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV)

## Interventions

24 children (aged 4-13 years able to take paediatric LPV/r tablets and either currently receiving LPV/r or about to start LPV/r containing ART) in a (1:1) ratio to LPV/r either in sprinkle or tablet formulation with food. After 4 weeks on allocated treatment children will have a 12 hour pharmacokinetic (PK) day with 7 blood draws (1.5-2.5ml each). Children will then switch LPV/r formulation to the other formulation (sprinkle or tablet) and continue to take that formulation with food for a further 4 weeks. At week 8, children will have a second 12 hour PK day of 7 blood draws (1.5-2.5ml each) after which children will choose which formulation of LPV/r they wish to remain on.

A third non-randomised intervention arm will include infants from 3 months to 1 year, already receiving or about to start LPV/r syrup with food. Infants will be followed for 4 weeks followed by a 12 hour PK day. They will then switch formulation to receive LPV/r sprinkle with food for 4 weeks followed by a second 12 hour PK day of 7 blood draws (1.5-2.5ml each) at week 8.

## **Intervention Type**

Other

## **Phase**

Phase I

## **Primary outcome measure**

1. To determine the pharmacokinetics (PK) of ritonavir-boosted-lopinavir (LPV/r) in a twice daily paediatric co-formulated fixed dose sprinkle combination (Lopimune, Cipla pharmaceuticals) and compare it to LPV/r in a twice daily paediatric co-formulated fixed dose tablet combination (Cipla Pharmaceuticals), both with food, in HIV-infected African children aged 4-12 years
2. To determine the pharmacokinetics (PK) of ritonavir-boosted-lopinavir (LPV/r) in a twice daily paediatric co-formulated fixed dose sprinkle combination (Lopimune, Cipla pharmaceuticals) and compare it to LPV/r in a twice daily paediatric co-formulated syrup (Abbott Pharmaceuticals), both with food, in HIV-infected African infants under 1 year of age

## **Secondary outcome measures**

1. To compare the formulation preferences of children and their carers in terms of sprinkle or tablets
2. To compare the formulation preferences of infants carers in terms of sprinkle or syrups
3. To evaluate the effects of age, sex, severity of illness and anthropometric measurements [weight-for-age, height-for-age, body mass index (BMI), middle upper arm circumference (MUAC) and malnutrition indices] on pharmacokinetic parameters for LPV/r in HIV-infected African children. Specifically, to examine whether malnutrition modifies the pharmacokinetic characteristics of boosted Protease Inhibitors (PIs).

## **Overall study start date**

15/04/2011

## **Completion date**

01/03/2012

# **Eligibility**

## **Key inclusion criteria**

1. Human immunodeficiency virus (HIV) infected infants aged 3 months to < 12 months currently taking or about to start Lopinavir/ritonavir (LPV/r) syrup based first-line following WHO

guidelines 2008 [7] or

2. HIV infected children able to swallow paediatric LPV/r tablets and aged 4-13 years and < 25Kg, currently taking or about to start LPV/r based second-line following WHO guidelines
2. Carers and children where appropriate, willing and able to give informed consent

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Children:

1. Who are expected to change weight bands (i.e. change dose) after enrollment and before PK day at week 8
2. With anaemia (haemoglobin < 8.5g/dL) or liver enzymes grade 2 or higher
3. With illnesses that could influence the pharmacokinetics of the antiretroviral (ARV) drugs at week 4 and week 8 e.g. severe diarrhoea, vomiting, renal or liver disease
4. On concomitant medications that are known to interact with the ARV drugs

**Date of first enrolment**

15/04/2011

**Date of final enrolment**

01/03/2012

**Locations****Countries of recruitment**

England

Uganda

United Kingdom

**Study participating centre**

**Medical Research Council**

London

United Kingdom

NW1 2DA

# Sponsor information

## Organisation

Medical Research Council (UK)

## Sponsor details

MRC Centre London  
Stephenson House  
158-160 North Gower Street  
London  
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## Sponsor type

Research council

## ROR

<https://ror.org/03x94j517>

# Funder(s)

## Funder type

Charity

## Funder Name

Monument Trust (UK) (ref: grant ID - MON4951)

# 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