

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

Submission date 28/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/04/2011	Condition category 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

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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
United Kingdom
NW1 2ND

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