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

Submission date 28/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/04/2011	**Overall study status** Completed	
Last Edited 28/04/2011	**Condition category** Infections and Infestations	

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 Oragnisation (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 pharmacokinetcis (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
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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