

Plasma pharmacokinetic study of once versus twice daily abacavir as part of combination antiretroviral therapy in children with human immunodeficiency virus-1 infection aged 3 months to less than 36 months

Submission date 07/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/07/2011	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=26

Study website

<http://www.pentatrials.org/trials.htm#penta15>

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

PENTA 15/Version 3.0

Study information

Scientific Title

Acronym

PENTA 15

Study objectives

Aim is to assess the pharmacokinetics, feasibility and acceptability of dosing abacavir (ABC) or ABC in combination with lamivudine (3TC) once daily in children aged 3 to less than 36 months.

Please note that the previous anticipated end date of this trial was 01/05/2007; the information held in this record was updated on the 17/09/2007 (from version 1.0 to version 3.0) at the request of the PI. The changes made for this version update included the above mentioned change to the anticipated end date, the addition of ethics approval, and a change to the countries of recruitment (which previously included Austria, Brazil, Germany, Ireland, Italy, Netherlands, Poland, Sweden, Thailand, United Kingdom, Argentina, Belgium, Denmark, France, Portugal, Romania, Spain, Switzerland).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Trent Multi-centre Research Ethics Committee (MREC) on 01/02/2006 (submitted 02/11/2005).

Study design

A non-randomised, cross-over, open label pharmacokinetic multi-centre study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Sample patient information sheet can be found in the full protocol at: http://www.pentatrials.org/p15_3_web.pdf

Health condition(s) or problem(s) studied

Paediatric HIV

Interventions

1. At week 0, while children enrolled in the study are on a twice-daily regimen containing ABC or ABC and 3TC, serial pharmacokinetic samples will be collected
2. Following collection of these samples, children will cross over and begin a regimen of ABC 16 mg/kg once-daily (and 3TC 8 mg/kg once-daily if applicable) for at least 12 weeks, with the second pharmacokinetic sample collected at week 4
3. The same daily dose will be maintained within 25% (allowing for dose adjustment for growth as appropriate)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Abacavir (ABC), Lamivudine (3TC)

Primary outcome measure

Area under curve (AUC), Cmin and Cmax values of ABC after once and twice daily dosing

Secondary outcome measures

1. AUC, Cmin and Cmax values of 3TC after once and twice daily dosing
2. Assessment of adherence and satisfaction with twice and once daily dosage regimens, using questionnaires

Overall study start date

01/01/2006

Completion date

01/06/2008

Eligibility

Key inclusion criteria

1. Infants and children with confirmed presence of human immunodeficiency virus (HIV-1) infection
2. Infants and children aged 3 to less than 36 months
3. Parents able/willing to give consent
4. Currently on combination anti-retroviral therapy (ART) including ABC oral solution or a combination of ABC and 3TC, for at least 12 weeks, and expected to stay on this regimen for at least a further 12 weeks
5. HIV-1 ribonucleic acid (RNA) viral load - either suppressed HIV-1 RNA viral load (i.e. less than

400 copies/ml) or non-suppressed but low HIV-1 RNA viral load (i.e. 400 - 20,000 copies/ml). The non-suppressed children should have had a stable or decreasing HIV-1 RNA viral load prior to study entry and should be considered to still be gaining benefit from the current regimen.
6. Children should have stable or rising cluster of differentiation-4 (CD4+) cell percentage prior to study entry and their CD4+ cell percentage should not be expected to fall within the next 12 weeks

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Months

Upper age limit

36 Months

Sex

Both

Target number of participants

18

Key exclusion criteria

1. Intercurrent illnesses
2. Receiving concomitant therapy except prophylactic antibiotics
3. Abnormal renal or liver function (grade 3 or above)

Date of first enrolment

01/01/2006

Date of final enrolment

01/06/2008

Locations**Countries of recruitment**

France

Germany

Italy

Spain

United Kingdom

Study participating centre
Clinica Pediatrica
Padova
Italy
35128

Sponsor information

Organisation
PENTA Foundation (Italy)

Sponsor details
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Sponsor type
Charity

Website
<http://www.ctu.mrc.ac.uk/penta>

ROR
<https://ror.org/00d7mpc92>

Funder(s)

Funder type
Government

Funder Name
PENTA Foundation (Italy) (mainly funded by the European Commission)

Funder Name
GlaxoSmithKline (USA)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No