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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

Registration date
17/01/2006

Last Edited
14/07/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=26

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
36 months

Sex
All

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
United Kingdom

France

Germany

Italy

Spain

Study participating centre
Clinica Pediatrica
Padova
Italy
35128

Sponsor information

Organisation
PENTA Foundation (Italy)

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., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes