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Therapeutic drug monitoring (TDM) in human immunodeficiency virus (HIV)-infected children starting a new anti-retroviral regime

Submission date
11/07/2003

Recruitment status
Stopped

Registration date
25/02/2004

Overall study status
Stopped

Last Edited
10/02/2011

Condition category
Infections and Infestations

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

Protocol serial number
PENTA 14

Study information

Scientific Title

Acronym
PENTA 14

Study objectives
1. To assess the effect of different levels of Therapeutic drug monitoring (TDM) compared with no TDM on plasma human immunodeficiency virus-1 ribonucleic acid (HIV-1 RNA) response in children starting or switching to a new highly active antiretroviral therapy (HAART) regimen including a protease inhibitor (PI) and/or non-nucleoside reverse transcriptase inhibitor (NNRTI)
2. To generate age-related population pharmacokinetic models for PIs and NNRTIs used in children
3. To describe the impact of a didactic adherence support tool for children taking HAART, which will be offered to centres participating in the trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paediatric HIV

Interventions
Full five point annual pharmacokinetic (PK) curve versus single sample PK versus no intervention. All children will receive additional adherence support.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The effect of the TDM strategies on viral load in terms of change in plasma HIV-1 RNA copies/ml from baseline to 96 weeks

Key secondary outcome(s))
1. The proportion of children who ever achieve plasma HIV-1 RNA <50 copies/ml, and who subsequently maintain plasma HIV-1 RNA <50 copies/ml to 96 weeks
2. Toxicity and tolerability of HAART

3. Adherence to HAART as assessed by caregiver completed questionnaire and CORALs
4. Progression to new AIDS defining event or death
5. Number of switches in antiretroviral therapy
6. The development of new genotypic resistance mutations by 96 weeks
7. Change in CD4% and CD4 count from baseline to week 96
8. Number of children in the target area for pharmacokinetic parameters after 12 weeks
9. Number of dosage adjustments based on pharmacokinetic parameters after 48 weeks

Completion date
01/11/2007

Reason abandoned (if study stopped)
Recruitment problems which were caused mainly by TDM being accepted as routine practice.

Eligibility

Key inclusion criteria
1. Confirmed HIV-infected, i.e. positive plasma HIV-1 RNA or deoxyribonucleic acid (DNA) test on two consecutive occasions (for children less than 18 months old), or positive HIV serology (for children aged 18 months and older), aged one month to 17 years inclusive
2. Parents/guardians, and children where appropriate, are willing and able to give informed consent
3. Plasma HIV-1 RNA viral load = 1000 copies/ml
4. Pre-treated children, including children who have received antiretroviral therapy only as prophylaxis to reduce mother to child transmission, who are prepared to wait for the results of a resistance test before starting new therapy
5. Starting antiretroviral therapy or switching to a new antiretroviral regimen considered likely to be highly active according to the results of a local resistance test, and containing either a PI or NNRTI or both; that is with at least two active drugs, one being a PI or NNRTI (active means not fully resistant)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 months

Upper age limit
17 years

Sex
All

Key exclusion criteria

Grade 3 or 4 creatinine or liver function tests

Date of first enrolment
01/07/2004

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
United Kingdom

Germany

Italy

Netherlands

Study participating centre
Clinica Pediatrica
Padova
Italy
35128

Sponsor information

Organisation
The Paediatric European Network for the treatment of AIDS (PENTA - Chair Dr Carlo Giaquinto)

ROR
https://ror.org/03ash3475

Funder(s)

Funder type
Government

Funder Name
European Union (EU) - grant (ref: QLK2-2000-00150)

Results and Publications

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes