ISRCTN14367816 https://doi.org/10.1186/ISRCTN14367816

PENTA8/ PERA (Paediatric Evaluation of Resistance Assays)

Submission date	Recruitment status	[_] Prospectively registered
03/01/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/01/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2008	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pentatrials.org/trials.htm#penpact1

Contact information

Type(s)
Scientific

Contact name
Prof Diana Gibb

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0)20 7670 4709
d.gibb@ctu.mrc.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

E528/26

Study information

Scientific Title

Acronym
PERA

Study objectives
To evaluate whether the use of resistance testing using a centralised genotypic assay with computer assisted interpretation (VIRCO 'virtual phenotype') to make decisions about a new regimen results in a greater reduction in human immunodeficiency virus (HIV)-1 RNA in HIV infected children than choice based on drug history and clinical factors alone

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Children randomised to Arm 1 will have access to a centralised genotypic assay, with computer assisted interpretation based on a database of linked results from genotypic and phenotypic testing.

Children randomised to Arm 2 will receive no resistance testing.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
The primary end-point is plasma HIV-1 RNA at 12 months measured in the central laboratory using the Roche ultra-sensitive assay (limit of detection 50 copies/ml)

Secondary outcome measures
1. Plasma HIV-1 RNA at 24 weeks
2. CD4 count adjusted for age at 12 months, measured locally
3. Antiretroviral therapy (ART) prescribed, in particular the number of switches in ART and drugs used
4. Adherence to ART prescribed (as measured by questionnaire)
5. Available drug options at 12 months
6. Progression to new acquired immunodeficiency syndrome (AIDS) defining event or death
7. Tolerability of, and adverse events to ART in the two arms
8. Proportion of children with viral load <50 copies/ml at 12 months

Overall study start date
01/06/2000

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Confirmed HIV-infected
2. Age 3 months to 18 years
3. Currently receiving and stable on the same antiretroviral therapy for at least 1 month; OR, if not on therapy, stopped within the last 2 weeks
4. Parents/guardians, and children where appropriate, are willing and able to give informed consent
5. Previous exposure to two or three classes of antiretroviral drugs, or, if exposed to nucleoside analogue reverse transcriptase inhibitors (NRTI) only, either exposed to three NRTI or two NRTI for more than 2 years
6. The paediatrician is likely to change treatment
7. Most recent HIV RNA result was >2000 copies/ml
8. Paediatrician and parents are willing to wait 3 weeks for the resistance assay result before switching therapy
9. Local resistance testing will not be done during the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
180, 170 recruited as of Sept 2006

Key exclusion criteria
1. A previous resistance test, assessing both reverse transcriptase and protease inhibitor drug resistance has been performed while the child is on the current regimen. Children who have had a test on a previous regimen may be enrolled to a maximum recruitment of 30 children.
2. Unlikely to comply with the routine schedule of visits

Date of first enrolment
01/06/2000

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Brazil

England

Germany

Italy

Portugal

Spain

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	01/01/2006		Yes	No