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# PENTA 16 Trial: short-cycle therapy (SCT) (5 days on/2 days off) in young people with chronic human immunodeficiency virus (HIV) infection

**Submission date**
27/05/2009

**Registration date**
05/08/2009

**Last Edited**
07/01/2019

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Infections and Infestations

[X] 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=78

**Study website**
http://www.pentatrials.org/home.htm

## Contact information

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Scientific

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# Additional identifiers

**EudraCT/CTIS number**
2009-012947-40

**IRAS number**

**ClinicalTrials.gov number**
NCT01641016

**Secondary identifying numbers**
HTA 08/53/25; PENTA 16 version 1.0

# Study information

**Scientific Title**
Short-cycle therapy (SCT) (5 days on/2 days off) in young people with chronic human immunodeficiency virus (HIV) infection: an open, randomised, parallel group, multicentre phase II /III trial

**Acronym**
PENTA 16

**Study objectives**
The overall aim of the PENTA 16 trial is to evaluate the role of short-cycle therapy (SCT) in the management of human immunodeficiency virus (HIV)-infected young people who have responded well to antiretroviral therapy and to determine whether young people undergoing SCT (five days on and two days off) maintain the same level of viral load suppression as those on continuous therapy, over 48 weeks.

The advantages and disadvantages of the strategy, the incidence of toxicities, immunological control, resistance mutations, acceptability, quality of life and adherence to the randomised strategy will also be compared.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/085325
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/52987/PRO-08-53-25.pdf

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Central London REC 4, 08/02/2010, ref: 10/H0714/8

## Study design
Open randomised parallel-group multicentre phase II/III trial

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Can be found at http://www.pentatrials.org/

## Health condition(s) or problem(s) studied
Infectious disease - Paediatric HIV

## Interventions
1. Short cycle therapy - 5 days on ART, 2 days off
2. Routine care - continuous ART

Once randomised participants will be followed for 48 weeks. However all participants will be followed (seen in clinic every 12 weeks) until the last patient to be randomised has completed week 48, therefore some participants will be followed for up to 3 years.

## Intervention Type
Drug

## Phase
Phase II/III

## Primary outcome measure
HIV-1 RNA greater than or equal to 50 c/ml (confirmed) at any of week 4, 8, 12, 24, 36 or 48

## Secondary outcome measures
1. HIV-1 RNA less than 50 c/ml at 24 and 48 weeks
2. Number of HIV mutations present at week 4, 8, 12, 24, 36 or 48 conferring resistance to drugs taken at randomisation or during the trial
3. Change in CD4 (absolute and percentage) from randomisation to 24 and 48 weeks
4. Change in ART (defined as any change from the ART regimen at randomisation)
5. ART-related grade 3 or 4 clinical and laboratory adverse events
6. New CDC stage C diagnosis or death
7. Changes in fasting cholesterol, triglycerides, low density lipoprotein (LDL), high density lipoprotein (HDL) and very low density lipoprotein (VLDL) levels through 48 weeks
8. Adherence, acceptability, and well-being over 48 weeks as assessed by patient completed questionnaires

### Overall study start date
25/03/2011

### Completion date
13/09/2016

# Eligibility

### Key inclusion criteria
Current inclusion criteria as of 16/01/2013
1. HIV-1 infected young people aged 8 to 24 years inclusive (Young people recruited between the ages of 16-21 must either be in regular physical contact with their clinician or be able to transfer to an adult physician at the same site for follow-up or to an affiliated adult site).
2. Parents/carers and/or young people, where applicable, willing to provide informed consent.
3. On a stable first-line ART treatment containing at least 2 NRTIs/NtRTIs and EFV for at least 12 months and willing to continue the regimen throughout the study period. Young people on regimens containing nevirapine (NVP) or a boosted protease inhibitor with undetectable viral load for over one year who wish to enrol should switch to EFV. Once they are stable on the EFV containing regimen for more than 12 weeks they may be enrolled (must have 2 subsequent HIV-1 RNA measurements <50 c/ml over a minimum period of 12 weeks). Previous dual therapy and /or substitution of NRTIs is allowed providing any changes were not for disease progression, immunological or virological failure (where virological failure is defined as two successive HIV-1 RNA results>1000 c/ml) subsequent to virological control having been achieved on ART.
4. Viral suppression (HIV-1 RNA <50 c/ml) for at least the prior 12 months (at least the last 3 measurements, including screening): young people who have experienced a single viral load >50 but <1000 copies/ml (preceded and followed by VL<50 c/ml) in the last 12 months can be enrolled.
5. CD4 cell count ≥350 106/L at screening visit.
6. Centre must routinely use an assay which detects HIV RNA-1 viral load ≥50 c/ml.

Previous inclusion criteria until 16/01/2013:
1. HIV-1 infected young people aged 8 to 21 years inclusive (Young people recruited between the ages of 16-21 must either be in regular physical contact with their clinician or be able to transfer to an adult physician at the same site for follow-up or to an affiliated adult site).

Previous inclusion criteria until 08/05/2012:
1. HIV-1 infected young people (either sex) aged 8 to 21 years inclusive (young people recruited between the ages of 16 - 21 years must either be in regular physical contact with their paediatrician or be able to transfer to an adult physician at the same site for follow-up or to an affiliated adult site)
2. Parents/carers and young people, where applicable, willing to provide informed consent
3. On a stable first-line anti-retroviral therapy (ART) regimen containing at least two nucleoside reverse transcriptase inhibitors (NRTIs) and efavirenz (EFV) for at least 12 months and willing to continue the regimen throughout the study period. Children on regimens containing nevirapine (NVP) or a boosted protease inhibitor with undetectable viral load wishing to enrol should switch to EFV, and may be enrolled if they have three subsequent HIV-1 ribonucleic acid (RNA) measurements less than 50 copies/ml over a minimum period of 12 weeks.
4. Viral suppression (HIV-1 RNA less than 50 copies/ml) for at least the prior 12 months (at least the last three measurements). Young people who have experienced a single viral load blip in the last 12 months can be enrolled; where the blip is defined as 'one or more detectable viral loads

(greater than or equal to 50 copies/ml) between two undetectable values (less than 50 c/ml) less than 9 months apart, during a period of sustained viral suppression'.
5. Started highly-active anti-retroviral therapy (HAART) naive (i.e. no previous mono- or dual-therapy unless for prevention of mother-to-child transmission)
6. May have experienced more than two classes of drug as long as change due to toxicity or simplification rather than due to virological failure (where virological failure is defined as two successive HIV-1 RNA results greater than 1000 c/ml (confirmed) more than 6 months after starting HAART)
7. CD4 cell count greater than or equal to 350 cells/µL at screening visit
8. Centre must routinely use an assay which detects HIV RNA-1 viral load greater than or equal to 50 copies/ml. Smaller blood sample requiring higher cut-off will be allowed.

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants
160 (80 in each arm)

### Key exclusion criteria
Current exclusion criteria as of 08/05/2012:
1. Pregnancy or risk of pregnancy in females of child-bearing potential.
2. Acute illness (young people may be enrolled after illness).
3. Receiving concomitant therapy for an acute illness (young people may be enrolled after finishing therapy).
4. A creatinine, AST or ALT of grade 3 or above at screening.
5. On a regimen including nevirapine or a boosted PI (young people may switch to an EFV based regimen).
6. Previous ART monotherapy (except for the prevention of mother-to-child transmission)

Previous exclusion criteria:
1. Pregnancy or risk of pregnancy in females of child bearing potential
2. Acute illness
3. Receiving concomitant therapy for an acute illness except antibiotic prophylaxis

### Date of first enrolment
25/03/2011

### Date of final enrolment
30/09/2014

## Locations

### Countries of recruitment
Argentina

Belgium

Denmark

England

Germany

Ireland

Spain

Thailand

Uganda

Ukraine

United Kingdom

United States of America

**Study participating centre**
**Aviation House**
London
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# Sponsor information

**Organisation**
PENTA Foundation (Italy)

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**Sponsor type**
Research organisation

**ROR**

https://ror.org/00d7mpc92

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**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 | 01/06/2016 | | Yes | No |
| Results article | results | 01/09/2016 | | Yes | No |
| Results article | results | 23/04/2018 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |