ISRCTN31541725 https://doi.org/10.1186/ISRCTN31541725

A randomised phase II trial to compare the toxicity, tolerability and activity of 2-drug combinations of the nucleoside analogue reverse transcriptase inhibitors (NRTIs) lamivudine ((-)2'-deoxy-3'thiacytidine, 3tc), zidovudine (ZDV) and 1592U89

Submission date 03/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/10/2000	**Overall study status** Completed	
Last Edited 07/11/2022	**Condition category** 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
G9627716

Study information

Scientific Title
A randomised phase II trial to compare the toxicity, tolerability and activity of 2-drug combinations of the nucleoside analogue reverse transcriptase inhibitors (NRTIs) lamivudine ((-) 2'-deoxy-3'thiacytidine, 3tc), zidovudine (ZDV) and 1592U89

Acronym
PENTA 5

Study objectives
Primary:
1. To compare the toxicity, tolerability and activity of three different 2-drug NRTI combinations in children taking either NFV or NFV placebo in Part A, and in those taking NFV in Part B. Activity will be assessed by effect on viral load measured by plasma HIV-1 RNA
2. To assess the tolerability and toxicity of NFV and NFV placebo in children in Part A

Secondary:
1. To compare the activity of NFV and NFV placebo in children taking one of the three 2-drug combinations in Part A
2. To describe the effect on viral resistance, CD4 cell count and clinical progression separately for the three NRTI groups and the NFV and NFV placebo groups
3. To compare the plasma viral load as measured by HIV-1 RNA in the 1592-containing arms with that in the non-1592 arms in children taking NFV or NFV placebo

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
Human Immunodeficiency Virus (HIV), Acquired Immunodeficiency Syndrome (AIDS)

Interventions
Three different 2-drug nucleoside analogue reverse transcriptase inhibitors (NRTI) combinations in children taking either nelfinavir (NFV) or nelfinavir (NFV) placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. To compare the combination of two NRTIs plus a protease inhibitor (PI) versus two NRTIs plus a non-nucleoside reverse transcriptase inhibitor (NNRTI) as initial therapy, followed by second-line therapy if virologic failure occurs, in terms of their effects on a long-term virologic endpoint
2. To compare two different viral load criteria for switching from first-line to second-line therapy

Secondary outcome measures
1. To evaluate and compare the safety and tolerability of each drug combination (including first- and second-line therapies)
2. To compare the long-term clinical and immunologic outcomes (by the initial randomization)
3. To compare the proportions of children who have undergone one regimen switch or reached study end-point (by the initial randomization)
4. To compare time from randomization to virologic failure (RNA >400 copies/ml at or after week 24) of the first-line therapy analyzed by initial randomization to either protease inhibitor (PI) or NNRTI containing regimens
5. To compare time from randomization to virologic failure of the second line therapy (RNA >30, 000 copies/ml) analyzed by the initial randomization
6. To compare the proportion of children with plasma HIV-1 RNA <400 copies/ml at 4 years (by the initial randomization)
7. To describe resistance patterns at 4 years (by the initial randomization)

Overall study start date
23/01/1998

Completion date
31/07/1999

Eligibility

Key inclusion criteria

1. 3 months to 16 years of age
2. Definitive HIV-1 infection

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
23/01/1998

Date of final enrolment
31/07/1999

Locations

Countries of recruitment
England

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		15/04/2000		Yes	No
Other publications		01/09/2001		Yes	No
Results article		02/03/2002		Yes	No
Results article		01/08/2002		Yes	No
Other publications		27/09/2002		Yes	No
Other publications	Adherence to prescribed antiretroviral therapy	01/01/2003		Yes	No
Other publications	5 year follow up	11/05/2007		Yes	No