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		
Registration date 03/10/2000	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
07/11/2022	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

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Contact details

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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