ISRCTN44582462 https://doi.org/10.1186/ISRCTN44582462

An open randomised trial to evaluate different therapeutic strategies of combination therapy for human immunodeficiency virus (HIV-1) Infection

Submission date
06/09/2005

Registration date
28/09/2005

Last Edited
10/07/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctu.mrc.ac.uk/initio/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title

Acronym
INITIO

Study objectives
To compare in patients starting therapy for HIV infection, the activity of three strategies for using anti-retroviral regimens for at least 3 years in terms of the effects on CD4 cell counts, plasma HIV RNA, viral resistance, progression of HIV disease and survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Protocol approved in Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, Switzerland, UK, Australia, New Zealand, Canada and Brazil.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
HIV-1 infection

Interventions
Randomisation of approximately 1000 participants, from 17 countries worldwide, to one of three drug regimens:
1. 2 NRTIs plus a NNRTI

2. 2 NRTIs plus a PI
3. 2 NRTIs plus a NNRTI and PI

Quality of life substudy:
Quality of life questionnaires to be completed by participants consenting to this substudy in participating countries.

Virology substudy:
Participants joining this substudy at participating sites will have plasma and cells taken for storage for further study.

Immunology substudy:
Participants joining this substudy from specified clinics, within 6-hour delivery time of the centralised immunology labs in five countries, UK, France, Australia, Switzerland and Italy, will have additional blood samples taken for detailed lymphocyte phenotypes, lymphoproliferative assays and CD8 T-cell specific activity. In addition, a tetanus toxoid vaccination will be given at week 24 for research purposes.

Lipodystrophy substudy:
Participants for this substudy will be recruited from Australia and at baseline, every 12 weeks and at first therapeutic failure, a patient assessment of body changes, fasting insulin, C-Peptide, fibrogen and plasminogen activator inhibitor and exercise level assessment will be taken. At baseline, every 24 weeks and at therapeutic failure a record will be made of: DEXA scan, single cut abdominal computed tomography (CT) scan, standardised anthropometry and an electrocardiogram (ECG).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Change in CD4 cell count between 2 and 3 years
2. The proportion of patients with plasma HIV RNA below 50 copies/ml at 3 years

Secondary outcome measures
1. Change in CD4 cell count between 2 and 3 years
2. Change in plasma HIV RNA at 3 years
3. The time on first regimen
4. Time on second regimen (where applicable)
5. The time to first plasma HIV RNA below 50 copies/ml
6. Phenotypic and genotypic drug resistance at 3 years
7. Progression of HIV disease (including death)

Overall study start date
01/03/1999

Completion date
31/03/2001

Eligibility

Key inclusion criteria
The participants in the trial must be HIV-1 infected, over 18 years of age, at any stage of HIV disease, but not acute symptomatic primary infection, where anti-retroviral therapy is indicated. Participants should be likely to take their first regimen for at least 6 months and be expected to adhere to the protocol.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. The participants must not have received prior treatment with antiretroviral drugs or immunotherapy
2. There must be no history of peripheral neuropathy or pancreatitis
3. Individuals must not be receiving combination cytotoxic chemotherapy for cancer or parental therapy for an active opportunistic infection
4. Women should not be pregnant, breastfeeding or unwilling to use adequate contraception
5. Participants will be ineligible if biochemistry and haematology blood results from screening are outside the trial upper safety limits.

Date of first enrolment
01/03/1999

Date of final enrolment
31/03/2001

Locations

Countries of recruitment
Australia

Belgium

Brazil

Canada

Denmark

England

Finland

France

Germany

Ireland

Italy

Luxembourg

New Zealand

Portugal

Spain

Sweden

Switzerland

United Kingdom

Study participating centre
MRC CTU
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
20 Park Cresent
London
United Kingdom
W1B 1AL

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Industry

Funder Name
The trial was supported with respect to funding, antiretroviral drugs, viral load assays and resistance assays by:

Funder Name
Dupont

Alternative Name(s)
DuPont Company, E. I. du Pont de Nemours and Company, E. I. du Pont de Nemours & Company, EI du Pont de Nemours Company, E.I. du Pont de Nemours and Co., EI DuPont de Nemours & Co., E.I. Dupont De Nemours and Company, EI DuPont de Nemours and Company, Inc., DuPont de Nemours, Inc., EI duPont de Nemours, DuPont de Nemours

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Hoffman-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Merck

Alternative Name(s)
Merck & Co., Inc., Merck & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Bristol Meyers Squibb

Funder Name
Medical Research Council

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

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Virco

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	22/07/2006		Yes	No