

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

Submission date 06/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2014	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Australia

Belgium

Brazil

Canada

Denmark

Finland

France

Germany

Ireland

Italy

Luxembourg

New Zealand

Portugal

Spain

Sweden

Switzerland

Study participating centre

MRC CTU

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (UK)

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, El du Pont de Nemours Company, E.I. du Pont de Nemours and Co., El DuPont de Nemours & Co., E.I. Dupont De Nemours and Company, El DuPont de Nemours and Company, Inc., DuPont de Nemours, Inc., El 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, Medical Research Committee and Advisory 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., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Virco

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/07/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes