

# 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

☐ Prospectively registered  
☐ Protocol

**Registration date**  
28/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan  
☒ Results

**Last Edited**  
10/07/2014

**Condition category**  
Infections and Infestations

☐ 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

### Contact name

Prof Abdel Babiker

### Contact details

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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 Crescent

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, 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, 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?
<a href="#">Results article</a>	results	22/07/2006		Yes	No