

An open randomised trial to evaluate the activity and tolerability of combinations of reverse transcriptase and protease inhibitors, including induction therapy, in individuals with Human Immunodeficiency Virus-1 (HIV-1) infection and CD4 cell counts greater than 25 x 10 to the power of 6 per litre

Submission date 03/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/09/2009	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9719167 (extension, ProCom trial)

Study information

Scientific Title

Acronym

The FORTE trial

Study objectives

To evaluate, in patients starting anti-HIV therapy, the activity over at least 48 weeks of two regimens in terms of effects on plasma HIV RNA, CD4 cell counts, viral resistance, progression of HIV disease and survival, and safety and tolerability.

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

HIV, Acquired Immunodeficiency Syndrome (AIDS)

Interventions

1. Didanosine (ddI), Stavudine (d4T), Nevirapine (NVP) plus Nelfinavir (NFV) for at least 24 weeks, then ddI, d4T and NVP as maintenance therapy
2. Continuous ddI, d4T plus NVP

Note: third arm with continuous ddl, d4T, NVP plus NFV deleted November 2000.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

2 regimens

Primary outcome measure

Virological failure defined as failure to achieve plasma HIV RNA less than 50 copies per millilitre during the first 24 weeks or, having achieved such a level of suppression, subsequent rebound of plasma HIV RNA above 400 copies per millilitre.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1999

Completion date

01/07/2002

Eligibility**Key inclusion criteria**

1. Age 18 years or more with documented HIV-1 infection and requiring anti-retroviral therapy
2. CD4 count greater than 25×10 to the power of 6 per litre
3. Any stage of HIV disease including recent infection (except acute symptomatic primary infection)
4. Likely to survive at least 2 years and take the allocated therapy for at least 6 months
5. Able to give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

1. Previous anti-retroviral treatment or immunotherapies
2. Peripheral nephropathy or a history of pancreatitis
3. Women who are pregnant, breastfeeding or not taking adequate contraception
4. Heterosexual men not willing to use barrier contraception
5. Receiving combination chemotherapy for cancer
6. Receiving parenteral therapy for an opportunistic infection
7. Unlikely to comply with the protocol
8. At screening with creatinine above upper limit of normal (ULN), ALT or AST above 2.5 times ULN, amylase above 1.5 times ULN (except if pancreatic amylase less than 1.5 times ULN), haemoglobin less than 10.5g/dl, neutrophils less than 1.0 or platelets less than 100

Date of first enrolment

01/10/1999

Date of final enrolment

01/07/2002

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

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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 (MRC) (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****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	01/10/2007		Yes	No