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 | Prospectively registeredProtocol |
|-----------------------------------|--|---|
| Registration date 03/10/2000 | Overall study status Completed | Statistical analysis plan[X] Results |
| Last Edited 29/09/2009 | Condition category Infections and Infestations | [] Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial numberG9719167 (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

Study type(s)

Not Specified

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 ddI, d4T, NVP plus NFV deleted November 2000.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

2 regimens

Primary outcome(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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 x 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre MRC Clinical Trials Unit London United Kingdom NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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

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 |