ISRCTN58987964 https://doi.org/10.1186/ISRCTN58987964

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

Registration date
03/10/2000

Overall study status
Completed

Last Edited
29/09/2009

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

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 ddI, 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 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

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
United Kingdom
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