ISRCTN78584791 https://doi.org/10.1186/ISRCTN78584791

Pilot study of simplification with fosamprenavir /ritonavir (FPV/r) monotherapy

Submission date	Recruitment status	[_] Prospectively registered
04/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2011	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Podzamczer

Contact details
HIV Unit
Infectious Disease Service
Hospital Universitari de Bellvitge
c/Feixa Llarga s/n
L'Hospitalet de Llobregat
Barcelona
Spain
08907
+34 93 26 07 668/667
dpodzamczer@bellvitgehospital.cat

Additional identifiers

Protocol serial number
FONT Study-07

Study information

Scientific Title

Simplification with fosamprenavir/ritonavir (FPV/r) monotherapy: a pilot, prospective one-arm non-comparative multicentre study

Acronym
FONT

Study objectives
Simplification with fosamprenavir/ritonavir (FPV/r) monotherapy in patients with undetectable viral load will maintain virological suppression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Hospital Bellvitge gave approval on the 27th September 2007 (amendment 1 on 13th December 2007)
2. Spanish Drug Agency approved the trial on the 27th September 2007

Primary study design
Interventional

Study design
Pilot, prospective one-arm non-comparative multicentre study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
Fosamprenavir/ritonavir 700/100 mg twice daily (BID). The duration of the study is 48 weeks. After the end of the study period, FPV/r monotherapy will be continued or not according to physicians criteria.

1. Discontinuation of nucleosides
2. Clinical and laboratory assessment at baseline and weeks 4, 8, 12, 16, 24, 32, 40 and 48. Tests include: blood cells, ALT, alkaline phosphatase, gamma-glutamyl transpeptidase (GGT), creatinine, triacylglycerol (TG), total cholesterol (TC), high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL), glucose, CD4 and CD8, viral load. At weeks 8 and 16 only viral load).
3. Pharmacokinetics (PK) and viral load in cerebrospinal fluid (CSF) sample at 24 weeks; same for semen samples at 0, 24 and 48 weeks
4. Genotype resistance tests if patients with viral load greater than 500 copies/mL throughout the study period

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fosamprenavir/ritonavir (FPV/r)

Primary outcome(s)
Proportion of patients with plasma viral load less than 40 copies/mL at 48 weeks.

Key secondary outcome(s)
1. Viral load in CSF and semen, in CSF sample at 24 weeks and in semen samples at 0, 24 and 48 weeks
2. FPV levels in CSF and semen, in CSF sample at 24 weeks and in semen samples at 0, 24 and 48 weeks
3. Correlation between FPV plasma viral load and virological and immunological responses
4. Immunological outcome (CD4 and CD8) at weeks 0, 4, 12, 24, 32, 40 and 48
5. Lipid changes at weeks 0, 4, 12, 24, 32, 40 and 48
6. Adherence to therapy (GEEMA questionnaire), every visit

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Adult human immunodeficiency virus (HIV) infected patients (greater than 18 years, either gender)
2. Receiving a highly active anti-retroviral therapy (HAART) regimen including FPV/r (for at least four weeks) and two nucleoside/nucleotide analogues
3. Without previous failure with protease inhibitor regimens
4. Viral load less than 40 copies/mL for at least six months
5. CD4 counts greater than 100 cells/uL at inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Previous virologic failure (confirmed or suspected) while receiving a PI-based regimen
2. Alanine aminotransferase (ALT) greater than 5 x upper limit of normal
3. Clinical suspicion of cirrosis

4. Renal insufficiency with glomerular filtrate less than 50 ml/min
5. Haemoglobin less than 9 g/dl
6. Neutrophils less than 1000/mm^3
7. Platelets less than 30,000 /mm^3
8. Pregnant women or no contraceptive measures
9. Active infection in the two weeks prior to inclusion in the study
10. Systemic therapy for neoplasms
11. Patients with positive hepatitis B surface antigens (HBsAg) receiving tenofovir and/or lamiduvine

Date of first enrolment
06/11/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Spain

Study participating centre
HIV Unit
Barcelona
Spain
08907

Sponsor information

Organisation
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

ROR
https://ror.org/0008xqs48

Funder(s)

Funder type
Research organisation

Funder Name

Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

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	01/08/2011		Yes	No