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Highly active anti-retroviral therapy including nevirapine once daily versus twice daily after at least 12 weeks of nevirapine twice daily. A randomized, open, multicentre trial.

Submission date
13/07/2006

Recruitment status
No longer recruiting

Registration date
28/07/2006

Overall study status
Completed

Last Edited
08/01/2021

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

Protocol serial number
NODy-03

Study information

Scientific Title
Highly active anti-retroviral therapy including nevirapine once daily versus twice daily after at least 12 weeks of nevirapine twice daily. A randomized, open, multicentre trial.

Acronym
NODy

Study objectives
Patients tolerating a standard nevirapine regimen for at least 12 weeks will not present greater hepatic toxicity if switched to a once daily regimen comparing with continuing the standard twice a day (bid) regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2003 by the Medicine Spanish Agency and the ethics boards of all participating hospitals.

Study design
Randomized, open, multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will be stratified according to whether their CD4 level is more than, equal to or less than 200 cells/ul and whether they are hepatitis C virus (HCV) positive or negative, and centrally randomized to one of these arms:
1. Switch to nevirapine 400 mg once daily
2. Continue with nevirapine 200 mg bid

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nevirapine

Primary outcome(s)

Proportion of patients with ALT or aspartate aminotransferase (AST) more than or equal to grade three (more than five times above normal values)

Key secondary outcome(s))
1. Time to ALT and time to AST to reach more than five times above baseline values
2. Virological (virological rebound), immunological (CD4 response) and clinical (progression to acquired immune deficiency syndrome [AIDS]) efficacy
3. Clinical hepatitis

Completion date
30/12/2006

Eligibility

Key inclusion criteria
1. Human immunodeficiency virus (HIV)-positive confirmed by Western blot
2. Adult 18 years or over
3. Under treatment with a highly active anti-retroviral therapy (HAART) regimen including nevirapine 200 mg bid for at least 12 weeks. Females with cluster of differentiation subset four molecules (CD4) >250 cells/ul need to have been receiving the nevirapine bid regimen for at least 18 weeks.
4. Alanine aminotransferase (ALT) <2.5 times the upper limit normal
5. Undetectable viral load (with the test used in each center)
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
289

Key exclusion criteria
1. Concomitant participation in another clinical trial
2. Clinical suspicion of hepatic cirrhosis
3. Renal failure with creatinine clearance <50 ml/min
4. Any of the following laboratory parameter alterations: amylases more than three times above normal values, haemoglobin <8 mg/dl, neutrophils <500 cells/ul, platelets <30,000/ul
5. Pregnancy

6. Active infection within the last four weeks
7. Treatment for neoplasms
8. Treatment with methadone

Date of first enrolment
30/04/2004

Date of final enrolment
30/12/2006

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
Industry

Funder Name
Boehringer Ingelheim, 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	01/04/2009	08/01/2021	Yes	No