

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	<input type="checkbox"/> Prospectively registered
Registration date 28/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2021	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

Contact name
Dr Daniel Podzamczar

Contact details
HIV Unit
Infectious Disease Service
Hospital Universitari de Bellvitge
Feixa Llarga s/n
L'Hospitalet de Llobregat
Barcelona
Spain
08907
+34 (0)93 260 7668
dpodzamczar@csb.scs.es

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