

# 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.

<b>Submission date</b> 13/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/01/2021	<b>Condition category</b> 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

30/04/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

308 (154 per arm)

**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)

**Sponsor details**

Av. Gran via s/n km 2,7  
L'Hospitalet de Llobregat  
Barcelona  
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08907

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.idibell.es>

**ROR**

<https://ror.org/0008xqs48>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Boehringer Ingelheim, Spain

## 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?
<a href="#">Results article</a>	results	01/04/2009	08/01/2021	Yes	No