

# Open multicentre, phase IV study to evaluate efficacy and safety of pegylated interferon alpha-2a (40 KD) plus ribavirin for chronic hepatitis C with normal transaminases in human immunodeficiency virus-infected patients

<b>Submission date</b> 29/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/10/2008	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
2006-001243-55

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

2006-001243-55

## **Study information**

**Scientific Title**

**Acronym**

CONTRA

**Study objectives**

Response of chronic hepatitis C with normal transaminases to the combined treatment of pegylated interferon and ribavirin in human immunodeficiency virus (HIV)-infected patients is not lower than that achieved in patients with elevated levels of transaminases.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The study was approved by the Reference Research Ethics Board of the IDIBELL, Hospital Universitari de Bellvitge on the 15th May 2006 (EudraCT no.: 2006-001243-55).

**Study design**

Open, multicentre of parallel groups

**Primary study design**

Interventional

**Secondary study design**

Multi-centre

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Human immunodeficiency virus/hepatitis C virus (HIV-HCV) co-infection

**Interventions**

Cases and controls will be treated with the combination of pegylated interferon alpha-2a plus ribavirin for 48 weeks. Treatment will be stopped at week 12 if, at least, 2-log decrease or negativity is not achieved at week 12.

Management of patients during treatment and follow-up will be the same for patients and controls.

**Intervention Type**

Drug

**Phase**

Phase IV

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

Pegylated interferon alpha-2a (40 KD), ribavirin

**Primary outcome measure**

Sustained virological response, defined as HCV-RNA less than 50 UI/mL 24 weeks after stopping treatment.

**Secondary outcome measures**

1. Percentage of patients with normal ALT levels 24 weeks after stopping treatment
2. Percentage of patients with early virological response, defined as negativity or 2-log decrease at week 12 of treatment

**Overall study start date**

01/05/2006

**Completion date**

31/12/2008

**Eligibility****Key inclusion criteria**

Cases:

1. HIV-infected patients
2. Older than 18 years
3. With chronic hepatitis C (positive serum hepatitis C virus-ribonucleic acid [HCV-RNA] and hepatitis C virus [HCV] antibody)
4. Persistent normal alanine aminotransferase (ALT)

Controls:

1. Adult HIV-infected patients
2. With chronic hepatitis C (positive serum HCV-RNA and HCV antibody)
3. Elevated ALT
4. Matched by sex, age, and HCV genotype

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

364 patients (182 cases and 182 controls)

**Key exclusion criteria**

Cases and controls:

1. Patients with hepatic cirrhosis Child B or C
2. CD4 counts less than 200 cells/mm<sup>3</sup>
3. Autoimmune diseases or any contraindication for treatment with interferon or ribavirin

**Date of first enrolment**

01/05/2006

**Date of final enrolment**

31/12/2008

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

C/Feixa Llarga s/n

Barcelona

Spain

8907

## **Sponsor information**

**Organisation**

Roche Farma S.A. (Spain)

**Sponsor details**

C/Eucalipto 33.

Madrid

Spain

28016

**Sponsor type**

Industry

**Website**

<http://www.roche.es/>

**ROR**

<https://ror.org/04b8zcj45>

**Funder(s)****Funder type**

Industry

**Funder Name**

Roche Farma S.A. (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