

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Miguel Santin

### Contact details

C/Feixa Llarga s/n  
Barcelona  
Spain  
8907  
+34 93 260 76 25  
msantin@csu.scs.es

## Additional identifiers

### Clinical Trials Information System (CTIS)

2006-001243-55

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Roche Farma S.A. (Spain)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration