

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

Submission date 29/05/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 27/10/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 27/10/2008	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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

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/mm³
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

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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