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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/10/2008	**Overall study status** Completed	
Last Edited 27/10/2008	**Condition category** Infections and Infestations	

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@csub.scs.es

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^3
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