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Effectiveness and safety of the treatment of chronic hepatitis C in patients infected with the human immunodeficiency virus comparing two types of pegylated interferon and ribavirin

Submission date
20/02/2006

Recruitment status
No longer recruiting

Registration date
10/05/2006

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
N/A

Study information

Scientific Title
Effectiveness and safety of the treatment of chronic hepatitis C in patients infected with the human immunodeficiency virus comparing two types of pegylated interferon and ribavirin

Acronym
PEGIFN-VHC/VIH

Study objectives
Provide data regarding efficiency and safety of treatment with two different kinds of pegylated-interferon (PEG-IFN) alpha-2b, in combination with ribavirin, of patients suffering from chronic hepatitis C without previous treatment and co-infected with human immunodeficiency virus (HIV).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Committee of Clinical Investigations, Hospital Clinic, Barcelona, Spain on 02/04/2003

Study design
Prospective, controlled, randomized, non-blinded, multicenter study in which the effectiveness and safety of the association of PEG-IFN alpha 2b and ribavirin versus PEG-IFN alpha 2a and ribavirin is evaluated.

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
Adult patients diagnosed with chronic compensated hepatitis C, without previous treatment and co-infected with HIV.

Interventions

The objective of this protocol is to obtain data on the effectiveness and safety of the combined treatment with pegylated-interferon alpha 2b and ribavirin in comparison with the combined treatment with pegylated-interferon alpha 2a and ribavirin, administered according to standard guidelines, in patients with chronic hepatitis C without prior treatment, co-infected with HIV and under anti-retroviral treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pegylated-interferon alpha 2a, pegylated-interferon alpha 2b and ribavirin

Primary outcome measure
To analyse the proportion of patients with sustained virological response maintained (HCV-RNA not detectable in plasma after 24 weeks to end the therapy)

Secondary outcome measures
1. To analyse the proportion of patients with a virological response (HCV-RNA not detectable or ≥2 log10 drop) after 12, 24, 34, 36, and 48 weeks of therapy
2. To analyse the tolerability and the safety of both treatments in the HIV-HCV co-infected patients
3. To analyse the clinical evolution of these patients
4. To determine parameters of quality of life in the treated patients
5. To evaluate the appearance and evolution of lipodystrophy
6. To evaluate the appearance of mitochondrial toxicity in the patients treated with nucleoside reverse transcriptase inhibitor (NRTI) plus ribavirine
7. To evaluate the histological response in the respondent patients as well as in the non-respondent ones

Overall study start date
01/05/2003

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Adult men or women 18-65 years of age
2. Chronic hepatitis C defined by elevated alanine transaminase (ALT) (1.5 times the upper limit of normal at least on two separate occasions over four weeks, before incorporation in the study
3. Anti-hepatitis C virus (anti-HCV) positive according to enzyme-linked immunosorbent assay (ELISA) and positive ribonucleic acid-hepatitis C virus (RNA-HCV) in serum by polymerase chain reaction (PCR)
4. Hepatic biopsy in the 18 months before inclusion in the study showing changes of chronic hepatitis, with or without cirrhosis

5. Compensated hepatopathy, with the following hematological and biochemical criteria:
a. Hemoglobin ≥11 g/dl in females and ≥12 g/dl in males
b. Total leucocytes ≥3,000 /mm^3 and neutrophyls ≥1,500 /mm^3
c. Platelets ≥ 80,000 /mm^3
d. Normal prothrombin time and plasmatic albumin
e. Normal bilirubin (unless other factors not related to hepatitis, such as Gilbert's disease, justify its elevation)
f. Normal serum creatinine (or <1.5 g/dl consistently in patients treated with indinavir) and normal uric acid
6. Absence of clinical signs, current or past, decompensation such as ascites, jaundice, hepatic encephalopathy or digestive hemorrhage by portal hypertension
7. HIV-infected - diagnosis by ELISA (two positive determinations or confirmed by western blotting test (WB) or RNA-HIV positive by PCR
8. Stable anti-retroviral treatment, with highly active anti-retroviral therapy (HAART) at least for 3 months
9. HIV viral load <50,000 copies/ml
10. Leucocyte basal count CD4+ >250 cel/mm^3
11. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Sample size 196 patients (98 for each arm of the study)

Total final enrolment
557

Key exclusion criteria
1. Any other cause of hepatopathy in the patient's history or in the biopsy (if applicable) different from chronic hepatitis C, among others
2. Infection by hepatitis B virus (HBsAg positive), primitive hemochromatosis, alpha-1 antitrypsin deficiency and Wilson's disease, autoimmune hepatitis, alcoholic hepatopathy, obesity induced hepatopathy, pharmacological hematopathy
3. Hemoglobinopathies included, among others, thalassemia (major and minor)
4. Decompensated hepatopathy defined by background or presence of ascites, bleeding varicose veins or spontaneous encephalopathy
5. Prior treatment of hepatitis C with any antiviral or immunomodulator medication, including ribavirin, thymosin and corticoids (when corticoids have been used only as treatment of

hepatopathy, not for other indications)
6. In female patients, pregnancy or breastfeeding
7. Any known disorder which may interfere with the patient's participation and with completion of the treatment or cause an increased risk of producing relevant side effects, such as:
a. Patients with chronic renal failure on hemodialysis
b. Psychiatric disorders, especially severe depression or other severe psychiatric disorders, such as major psychosis, suicidal ideas and/or suicide attempt
The following is understood to be severe depression:
a. Individuals that have been hospitalized due to depression
b. Individuals who have received electroconvulsive therapy for depression
c. Individuals whose depression has caused a prolonged work absence and/or significant alteration of daily activities. It may be possible to consider including in the study individuals with a background of mild depression as long as an evaluation of their mental state prior to the treatment confirms that they are clinically stable.
8. Patients being treated with efavirenz, except if the patient has been treated with said medication for more than three months and has been assessed positively by a psychiatrist
9. Central nervous system (CNS) traumatism or active epilepsy requiring medication
10. Significant cardiovascular dysfunction six months before (e.g. angina, congestive cardiac failure, recent myocardial infarction, severe hypertension or significant arrhythmia) or significant alteration in the echocardiogram (ECG)
11. Badly controlled diabetes mellitus
12. Chronic pulmonary disease (e.g. chronic obstructive pulmonary disease)
13. Autoimmune disease (e.g. intestinal inflammatory disease, thromboticytopecnic purpura, systemic lupus erythematosus, autoimmune hemolytic anemia, scleroderma, severe psoriasis)
14. Substance abuse such as alcohol (≥80 g /day), inhalated or intravenously (IV)-administered drugs. If the individual has a background of substance abuse and is a candidate for inclusion in the protocol, he/she must have abstained from said drug for at least a year.
15. Clinically significant retinal anomalies
16. Any other disorder that, in the opinion of the researcher, makes the patient inappropriate for recruitment or may interfere with his participation and completion of the study

Date of first enrolment
01/05/2003

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Spain

Study participating centre
Infectious Diseases Service
Barcelona
Spain
08036

Sponsor information

Organisation
Barcelona Hospital Clinic Villarroel (Spain)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Infectious Diseases Service, Hospital Clínic, Villarroel, 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?
Results article	results	01/06/2009	11/01/2021	Yes	No