ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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A Study of PEGASYS (Pegylated-interferon Alfa-2a) With or Without Ribavirin in Patients With Chronic Hepatitis C Who Have Participated in Previous Roche or Roche Partner Protocols

This study has been completed.

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by (Responsible Party):	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT00800735

Purpose

This single arm study will provide treatment or re-treatment with PEGASYS as monotherapy or in combination with ribavirin (Copegus), to patients with chronic hepatitis C (CHC) who have participated in a previous Roche or Roche partner protocol where access to treatment or re-treatment was promised or deemed appropriate following completion of the original protocol ('donor' protocol). Patients who qualify for treatment or re-treatment will begin PEGASYS monotherapy, at a maximum dose of 180 µg weekly, or combination therapy with Copegus, 800-1200 mg daily, as continuation of treatment after the wash-out period defined in their donor protocol. PEGASYS treatment is not to exceed the approved treatment duration of 48 weeks in genotype G1 with a treatment-free follow up period of 24 weeks.

Condition	Intervention	Phase
Hepatitis C, Chronic	Drug: Pegylated-interferon alfa-2a Drug: Ribavirin	Phase 3

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety Study

Official Title: An Open-label, Multicenter Protocol Providing Pegylated-interferon Alfa-2a (PEGASYS®) as Monotherapy or in Combination With Ribavirin (COPEGUS®) for Patients With Chronic Hepatitis C Who Have Participated in Previous Roche or Roche Partner Protocols

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Percentage of Participants Who Experienced at Least 1 Adverse Event. [Time Frame: Baseline through 24 weeks after the end of treatment (up to 72 weeks)] [Designated as safety issue: Yes]

  An adverse event is any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.

Enrollment: 30
Study Start Date: April 2009
Primary Completion Date: March 2012
Study Completion Date: March 2012

Arms	Assigned Interventions
Experimental: Pegylated-interferon alfa-2a plus ribavirin Participants received pegylated-interferon alfa-2a 180 µg/week subcutaneously plus ribavirin 1000 mg/day orally for patients weighing < 75 kg or 1200 mg/day for patients weighing ≥ 75 kg for 48 weeks.	Drug: Pegylated-interferon alfa-2a Pegylated-interferon alfa-2a was administered subcutaneously once weekly. Other Names: PEG-IFN alfa-2a Pegasys Drug: Ribavirin Participants received ribavirin with food, as the bioavailability of ribavirin is increased when taken with food. Ribavirin was administered as split doses, that is, 2 doses were given 12 hours apart, 1 in the morning and 1 in the evening. Participants received either 1000 or 1200 mg ribavirin per day according to body weight: 400 mg (2 tablets) in the morning and 600 mg (3 tablets) in the evening for participants weighing < 75 kg or 600 mg (3 tablets) in the morning and 600 mg (3 tablets) in the evening for participants weighing ≥ 75 kg. Other Names: Copegus Ro 20-9963

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Adult patients, ≥ 18 years of age.
- Chronic hepatitis C (CHC) patients with compensated liver disease (Child-Pugh A) who have participated in a donor protocol where access to treatment or re-treatment with PEGASYS monotherapy or in combination with Copegus was promised or deemed appropriate after completion of the donor protocol.

Exclusion Criteria:

- Evidence of decompensated liver disease (Child B or C cirrhosis).

Contacts and Locations

Locations

United States, California
Sacramento, California, United States, 95817
San Francisco, California, United States, 94115
United States, Maryland
Lutherville, Maryland, United States, 21093
United States, New York
Manhasset, New York, United States, 11030
New York, New York, United States, 10021
United States, North Carolina
Chapel Hill, North Carolina, United States, 27599-7584
United States, Oregon
Portland, Oregon, United States, 97239
United States, Rhode Island
Providence, Rhode Island, United States, 02905
United States, Tennessee
Nashville, Tennessee, United States, 37203
United States, Texas
San Antonio, Texas, United States, 78215
United States, Utah
Salt Lake City, Utah, United States, 84132
Austria
Wien, Austria, 1090
Canada, British Columbia
Vancouver, British Columbia, Canada, V5Z 1H2
Vancouver, British Columbia, Canada, V5Z 1M9
Canada, Ontario
Toronto, Ontario, Canada, M5G 1L7

France
Clichy, France, 92118
Germany
Berlin, Germany, 10969
Frankfurt Am Main, Germany, 60590
Koeln, Germany, 50924
Spain
Badalona, Spain, 08915
Barcelona, Spain, 08003
Madrid, Spain, 28222
Valencia, Spain, 46014

Investigators

Study Director:	Clinical Trials	Hoffmann-La Roche

More Information

Responsible Party:	Hoffmann-La Roche
Study ID Numbers:	NV21928 2008-002022-10
Health Authority:	United States: Food and Drug Administration

Study Results

Participant Flow

Reporting Groups

	Description
Pegylated-interferon Alfa-2a Plus Ribavirin	Participants received pegylated-interferon alfa-2a 180 µg/week subcutaneously plus ribavirin 1000 mg/day orally for patients weighing < 75 kg or 1200 mg/day for patients weighing ≥ 75 kg for 48 weeks.

Overall Study

	Pegylated-interferon Alfa-2a Plus Ribavirin
Started	30
Completed	16
Not Completed	14
Administrative/Other	2

	Pegylated-interferon Alfa-2a Plus Ribavirin
Insufficient Therapeutic Response	2
Violation of Selection Criteria at Entry	7
Withdrew Consent	3

Baseline Characteristics

Reporting Groups

	Description
Pegylated-interferon Alfa-2a Plus Ribavirin	Participants received pegylated-interferon alfa-2a 180 µg/week subcutaneously plus ribavirin 1000 mg/day orally for patients weighing < 75 kg or 1200 mg/day for patients weighing ≥ 75 kg for 48 weeks.

Baseline Measures

	Pegylated-interferon Alfa-2a Plus Ribavirin
Number of Participants	30
Age, Continuous [units: years] Mean (Standard Deviation)	48.5 (9.35)
Gender, Male/Female [units: participants]	
Female	18
Male	12
Race/Ethnicity, Customized [units: participants]	
Black	2
Caucasian	28
Height [units: cm] Mean (Standard Deviation)	170.0 (7.28)
Weight [units: kg] Mean (Standard Deviation)	76.97 (16.146)
Body Mass Index (BMI) [units: kg/m^2] Mean (Standard Deviation)	26.5 (4.53)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Experienced at Least 1 Adverse Event.
Measure Description	An adverse event is any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.
Time Frame	Baseline through 24 weeks after the end of treatment (up to 72 weeks)
Safety Issue?	Yes

Analysis Population Description

All enrolled patients.

Reporting Groups

	Description
Pegylated-interferon Alfa-2a Plus Ribavirin	Participants received pegylated-interferon alfa-2a 180 µg/week subcutaneously plus ribavirin 1000 mg/day orally for patients weighing < 75 kg or 1200 mg/day for patients weighing ≥ 75 kg for 48 weeks.

Measured Values

	Pegylated-interferon Alfa-2a Plus Ribavirin
Number of Participants Analyzed	30
Percentage of Participants Who Experienced at Least 1 Adverse Event. [units: Percentage of participants]	80.0

Reported Adverse Events

Time Frame	Adverse events from the beginning of treatment up to 24 weeks after the end of treatment were reported.
Additional Description	Safety population: All enrolled participants.

Reporting Groups

	Description
Pegylated-interferon Alfa-2a Plus Ribavirin	Participants received pegylated-interferon alfa-2a 180 µg/week subcutaneously plus ribavirin 1000 mg/day orally for patients weighing < 75 kg or 1200 mg/day for patients weighing ≥ 75 kg for 48 weeks.

Serious Adverse Events

	Pegylated-interferon Alfa-2a Plus Ribavirin
	Affected/At Risk (%)
Total	4/30 (13.33%)
Eye disorders	
Retinal haemorrhage †	1/30 (3.33%)
Infections and infestations	
Conjunctivitis viral †	1/30 (3.33%)
Laryngitis †	1/30 (3.33%)
Sinusitis †	1/30 (3.33%)
Injury, poisoning and procedural complications	
Arthropod bite †	1/30 (3.33%)
Rib fracture †	1/30 (3.33%)
Investigations	
Prothrombin time prolonged †	1/30 (3.33%)
Respiratory, thoracic and mediastinal disorders	
Haemoptysis †	1/30 (3.33%)

† Indicates events were collected by systematic assessment.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Pegylated-interferon Alfa-2a Plus Ribavirin
	Affected/At Risk (%)
Total	23/30 (76.67%)
Blood and lymphatic system disorders	
Anaemia †	4/30 (13.33%)

	Pegylated-interferon Alfa-2a Plus Ribavirin
	Affected/At Risk (%)
Lymphopenia †	4/30 (13.33%)
Endocrine disorders	
Hyperthyroidism †	2/30 (6.67%)
Gastrointestinal disorders	
Dyspepsia †	3/30 (10%)
Nausea †	8/30 (26.67%)
Vomiting †	3/30 (10%)
General disorders	
Asthenia †	5/30 (16.67%)
Chills †	7/30 (23.33%)
Fatigue †	16/30 (53.33%)
Influenza like illness †	5/30 (16.67%)
Pyrexia †	4/30 (13.33%)
Infections and infestations	
Bronchitis †	4/30 (13.33%)
Sinusitis †	2/30 (6.67%)
Urinary tract infection †	2/30 (6.67%)
Metabolism and nutrition disorders	
Decreased appetite †	3/30 (10%)
Musculoskeletal and connective tissue disorders	
Arthralgia †	4/30 (13.33%)
Back pain †	2/30 (6.67%)
Myalgia †	4/30 (13.33%)
Nervous system disorders	
Dizziness †	2/30 (6.67%)
Headache †	7/30 (23.33%)

	Pegylated-interferon Alfa-2a Plus Ribavirin
	Affected/At Risk (%)
Psychiatric disorders	
Depression †	5/30 (16.67%)
Insomnia †	7/30 (23.33%)
Respiratory, thoracic and mediastinal disorders	
Cough †	4/30 (13.33%)
Dyspnoea †	3/30 (10%)
Skin and subcutaneous tissue disorders	
Alopecia †	5/30 (16.67%)
Dry skin †	5/30 (16.67%)
Pruritus †	9/30 (30%)
Rash †	6/30 (20%)

† Indicates events were collected by systematic assessment.

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

Name/Official Title: Medical Communications
Organization: Hoffmann-La Roche
Phone: 800 821-8590
Email: