ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 9, 2016

ClinicalTrials.gov ID: NCT02806505

Study Identification

Unique Protocol ID:	MV17149
Brief Title:	HELPS Study - A Study of Peginterferon Alfa-2a (Pegasys) in Patients With Chronic Hepatitis C (CHC) and End-Stage Renal Disease (ESRD)
Official Title:	A Randomized, Open-Label, Multicenter, Parallel Group Study Evaluating the Efficacy and Safety of 135 µg and 90 µg of PEGASYS® Given as Monotherapy to Patients With Chronic Hepatitis C and End-Stage Renal Disease Undergoing Hemodialysis
Secondary IDs:	

Study Status

Record Verification:	September 2016
Overall Status:	Completed
Study Start:	June 2004
Primary Completion:	August 2007 [Actual]
Study Completion:	August 2007 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 4/13/2004 Board Name: Comite Consultatif de Protection des Personnes dans la Recherche Biomedicale de Bicetre Board Affiliation: Hopital Bicetre Phone: +33 (0)145 212846 Email:
Data Monitoring?:	
Plan to Share IPD?:	
Oversight Authorities:	France: National Agency for Drug Safety (ANSM)

Study Description

Brief Summary:	This study evaluated the safety and efficacy of peginterferon alfa-2a monotherapy in participants with Chronic Hepatitis C (CHC) who have End-Stage Renal Disease (ESRD) and were undergoing hemodialysis.
Detailed Description:	

Conditions

Conditions:	Hepatitis C, Chronic
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2

Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	81 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Peginterferon alfa-2a 135 microgram (mcg) Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.	Drug: Peginterferon alfa-2a Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a either 135 or 90 mcg SC once weekly up to Week 48. Other Names: • Pegasys
Experimental: Peginterferon alfa-2a 90 mcg Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.	Drug: Peginterferon alfa-2a Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a either 135 or 90 mcg SC once weekly up to Week 48. Other Names: • Pegasys

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	65 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Serum hepatitis C virus ribonucleic acid (HCV RNA) quantifiable at greater than (>) 600 IU/mL
- Liver biopsy consistent with chronic hepatitis C infection obtained within 2 years of enrollment
- Compensated liver disease without cirrhosis
- Participants with end-stage renal disease undergoing hemodialysis

- Negative serum pregnancy test (for women of childbearing potential) documented within the 24-hour period prior to the first dose of study drug
- All fertile participants must have been using effective contraception during treatment with study drug

Exclusion Criteria:

- Interferon therapy at any previous time
- Liver cirrhosis
- Signs and symptoms of hepatocellular carcinoma
- History or other evidence of decompensated liver disease
- Any investigational drug less than or equal to 6 weeks prior to the first dose of study drug
- History or other evidence of a medical condition associated with chronic liver disease other than HCV (e.g., hemochromatosis, autoimmune hepatitis, metabolic liver disease, alcoholic liver disease, toxin exposures)
- Poorly controlled diabetes
- Thyroid dysfunction not adequately controlled
- Evidence of severe retinopathy or clinically relevant ophthalmological disorder
- Severe hyperparathyroidism defined as intact Parathyroid Hormone (PTH) > 800 picogram/milliliter (pg/mL)
- Therapy with any systemic anti-viral, anti-neoplastic or immunomodulatory treatment ≤ 6 months prior to the first dose of study drug
- Acute renal failure
- Women with ongoing pregnancy or breast feeding
- Positive test at screening for anti-HAV IgM Ab (hepatitis A virus immunoglobulin M antibody), hepatitis B surface antigen (HBsAg), anti-HBc (hepatitis B core) IgM Ab, anti-HIV (human immunodeficiency virus) Ab

Contacts/Locations

Study Officials: Clinical Trials
Study Chair
Hoffmann-La Roche

Locations: Austria
Graz, Austria, 8036

Wien, Austria, 1090

Brazil
Brasilia, Brazil, 70335-000

Porto Alegre, Brazil, 90035-003

Sao Luis, Brazil, 78048-790

Sao Jose Rio Preto, Brazil, 15090-003

Sao Paulo, Brazil, 04023-900

France
Creteil, France, 94010

Le Kremlin-bicetre, France, 94275

Marseille, France, 13385

Paris, France, 75747

Strasbourg, France, 67091

Toulouse, France, 31059

Greece
Athens, Greece, 11527

Nikea, Greece, 18354

Indonesia
Medan, Indonesia, 20119

Italy
Cagliari, Italy, 09134

Turkey
Istanbul, Turkey, 34390

Istanbul, Turkey, 34662

Istanbul, Turkey, 34303

Izmir, Turkey, 35040

United Arab Emirates
Abu Dhabi, United Arab Emirates

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Pre-Assignment Details	A total of 85 participants were randomly assigned to the two treatment groups (Peginterferon alfa-2a 135 mcg/ week and Peginterferon alfa-2a 90 mcg/week). A total of 4 randomized participants did not receive any study drug.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Overall Study

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
Started	38	43
Completed	28	32
Not Completed	10	11
Adverse event/ intercurrent illness	1	3
Death	4	0
Did not cooperate/ refused treatment	3	3
Failure to return	0	1
Insufficient therapeutic response	2	4

Baseline Characteristics

Baseline Analysis Population Description

The intent-to-treat (ITT) analysis population included all the randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Baseline Measures

		Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg	Total
Overall Number of Participants		38	43	81
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	38 participants	43 participants	81 participants
		44.2 (11.26)	42.9 (11.26)	43.5 (11.21)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	38 participants	43 participants	81 participants
	Female	15 39.47%	9 20.93%	24 29.63%
	Male	23 60.53%	34 79.07%	57 70.37%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Sustained Virological Response (SVR) at 24 Weeks After End of Treatment
Measure Description	SVR was defined as the percentage of patients with undetectable HCV RNA. SVR rate was calculated as the number of participants with an undetectable HCV RNA divided by the number of participants of the respective participant population. The last single HCV RNA less than (<) 50 international units per millilitre (IU/mL) measured >=140 days after treatment end (i.e., >= 20 weeks after treatment end) was used to determine SVR. Participants without measurements in this time window were considered to be nonresponders.
Time Frame	24 weeks after end of treatment (Week 72)

Safety Issue?	No

Analysis Population Description

The ITT analysis population included all the randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Measured Values

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
Number of Participants Analyzed	38	43
Percentage of Participants With Sustained Virological Response (SVR) at 24 Weeks After End of Treatment Number (95% Confidence Interval) Unit of measure: percentage of participants	39.5 (24.0 to 56.6)	34.9 (21.0 to 50.9)

Statistical Analysis 1 for Percentage of Participants With Sustained Virological Response (SVR) at 24 Weeks After End of Treatment

Statistical Analysis Overview	Comparison Groups	Peginterferon Alfa-2a 135 Microgram (mcg), Peginterferon Alfa-2a 90 mcg
	Comments	The odds ratio is the ratio of the odds of a response in the Peginterferon alfa-2a 135 mcg group with the odds of a response in the Peginterferon alfa-2a 90 mcg group.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6746
	Comments	Assessed by Cochran-Mantel-Haenszel test stratified by country (Brazil, France, Other) and HCV genotype (1 vs. non-1).
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.22
	Confidence Interval	(2-Sided) 95% 0.49 to 3.06
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Virological Response (Non-detectable Hepatitis C Virus-ribonucleic Acid [HCV RNA]) at End of Treatment (EOT)
Measure Description	Virological response at the end of study treatment was defined as the percentage of participants with undetectable HCV RNA. This response rate at end of treatment was calculated as the number of participants with undetectable HCV RNA divided by the number of participants of the respective participant population.
Time Frame	EOT (Week 48)
Safety Issue?	No

Analysis Population Description

The ITT analysis population included all the randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Measured Values

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
Number of Participants Analyzed	38	43
Percentage of Participants With Virological Response (Non-detectable Hepatitis C Virus-ribonucleic Acid [HCV RNA]) at End of Treatment (EOT) Number (95% Confidence Interval) Unit of measure: percentage of participants	57.9 (40.8 to 73.7)	48.8 (33.3 to 64.5)

Statistical Analysis 1 for Percentage of Participants With Virological Response (Non-detectable Hepatitis C Virus-ribonucleic Acid [HCV RNA]) at End of Treatment (EOT)

Statistical Analysis Overview	Comparison Groups	Peginterferon Alfa-2a 135 Microgram (mcg), Peginterferon Alfa-2a 90 mcg
	Comments	The odds ratio is the ratio of the odds of a response in the Peginterferon alfa-2a 135 mcg group with the odds of a response in the Peginterferon alfa-2a 90 mcg group.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3923
	Comments	Assessed by Cochran-Mantel-Haenszel test stratified by country (Brazil, France, Other) and HCV genotype (1 vs. non-1).
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.51
	Confidence Interval	(2-Sided) 95% 0.60 to 3.76
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Virological Response (at Least a 2-log 10 Decrease in HCV RNA as Compared With Baseline or Unquantifiable [Less Than {<} 600 International Unit/Milliliter {IU/mL}] or Undetectable HCV RNA [< 50 IU/mL]) at Week 12 and 24
Measure Description	Virological response at Weeks 12 and 24 was computed as the percentage of participants with at least a 2-log 10 decrease in HCV RNA at Weeks 12 and 24 as compared with baseline or with an unquantifiable (< 600 IU/mL) or an undetectable HCV RNA test result (< 50 IU/mL) at Week 12 and at Week 24, calculated as the number of participants meeting this criterion divided by the number of participants of the respective participant population.
Time Frame	Weeks 12 and 24
Safety Issue?	No

Analysis Population Description

The ITT analysis population included all the randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Measured Values

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
Number of Participants Analyzed	38	43
Percentage of Participants With Virological Response (at Least a 2-log 10 Decrease in HCV RNA as Compared With Baseline or Unquantifiable [Less Than {<} 600 International Unit/Milliliter {IU/mL}] or Undetectable HCV RNA [< 50 IU/mL]) at Week 12 and 24 Number (95% Confidence Interval) Unit of measure: percentage of participants		
Week 12	71.1 (54.1 to 84.6)	69.8 (53.9 to 82.8)
Week 24	65.8 (48.6 to 80.4)	72.1 (56.3 to 84.7)

Statistical Analysis 1 for Percentage of Participants With Virological Response (at Least a 2-log 10 Decrease in HCV RNA as Compared With Baseline or Unquantifiable [Less Than {<} 600 International Unit/Milliliter {IU/mL}] or Undetectable HCV RNA [< 50 IU/mL]) at Week 12 and 24

Statistical Analysis Overview	Comparison Groups	Peginterferon Alfa-2a 135 Microgram (mcg), Peginterferon Alfa-2a 90 mcg
	Comments	Week 12: The odds ratio is the ratio of the odds of a response in the Peginterferon alfa-2a 135 mcg group with the odds of a response in the Peginterferon alfa-2a 90 mcg group.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8843
	Comments	Assessed by Cochran-Mantel-Haenszel test stratified by country (Brazil, France, Other) and HCV genotype (1 vs. non-1).
	Method	Cochran-Mantel-Haenszel

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.07
	Confidence Interval	(2-Sided) 95% 0.43 to 2.68
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percentage of Participants With Virological Response (at Least a 2-log 10 Decrease in HCV RNA as Compared With Baseline or Unquantifiable [Less Than {<} 600 International Unit/Milliliter {IU/mL}] or Undetectable HCV RNA [< 50 IU/mL]) at Week 12 and 24

Statistical Analysis Overview	Comparison Groups	Peginterferon Alfa-2a 135 Microgram (mcg), Peginterferon Alfa-2a 90 mcg
	Comments	Week 24: The odds ratio is the ratio of the odds of a response in the Peginterferon alfa-2a 135 mcg group with the odds of a response in the Peginterferon alfa-2a 90 mcg group.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5866
	Comments	Assessed by Cochran-Mantel-Haenszel test stratified by country (Brazil, France, Other) and HCV genotype (1 vs. non-1).
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.75
	Confidence Interval	(2-Sided) 95% 0.28 to 2.04
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	Baseline up to follow up period (Week 72)
Additional Description	An adverse event was defined as any untoward medical occurrence that occurred during the course of the trial after study treatment had started.

Reporting Groups

	Description
Peginterferon Alfa-2a 135 Microgram (mcg)	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 135 mcg subcutaneously (SC) once weekly up to Week 48.
Peginterferon Alfa-2a 90 mcg	Chronic Hepatitis C participants with end-stage renal disease undergoing hemodialysis will receive Peginterferon alfa-2a 90 mcg SC once weekly up to Week 48.

Serious Adverse Events

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	14/38 (36.84%)	14/43 (32.56%)
Blood and lymphatic system disorders		
Anaemia [A] †	0/38 (0%)	1/43 (2.33%)
Cardiac disorders		
Acute coronary syndrome [A] †	1/38 (2.63%)	0/43 (0%)
Cardiac failure [A] †	1/38 (2.63%)	0/43 (0%)
Coronary artery disease [A] †	1/38 (2.63%)	1/43 (2.33%)
Coronary artery stenosis [A] †	0/38 (0%)	1/43 (2.33%)
Hypertrophic cardiomyopathy [A] †	1/38 (2.63%)	0/43 (0%)
Ventricle rupture [A] †	1/38 (2.63%)	0/43 (0%)
Congenital, familial and genetic disorders		
Gene mutation [A] †	0/38 (0%)	1/43 (2.33%)
Endocrine disorders		
Hyperparathyroidism secondary [A] †	0/38 (0%)	2/43 (4.65%)
Gastrointestinal disorders		
Abdominal pain [A] †	1/38 (2.63%)	0/43 (0%)
General disorders		
Chest pain [A] †	1/38 (2.63%)	0/43 (0%)

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Multi-organ failure [A] †	1/38 (2.63%)	0/43 (0%)
Immune system disorders		
Transplant rejection [A] †	0/38 (0%)	1/43 (2.33%)
Infections and infestations		
Arthritis bacterial [A] †	1/38 (2.63%)	0/43 (0%)
Bacterial infection [A] †	1/38 (2.63%)	0/43 (0%)
Endocarditis [A] †	1/38 (2.63%)	0/43 (0%)
Pneumonia [A] †	1/38 (2.63%)	2/43 (4.65%)
Sepsis [A] †	2/38 (5.26%)	1/43 (2.33%)
Urinary tract infection [A] †	0/38 (0%)	1/43 (2.33%)
Viral infection [A] †	1/38 (2.63%)	0/43 (0%)
Injury, poisoning and procedural complications		
Arteriovenous fistula site complication [A] †	0/38 (0%)	1/43 (2.33%)
Poisoning [A] †	1/38 (2.63%)	0/43 (0%)
Road traffic accident [A] †	0/38 (0%)	1/43 (2.33%)
Investigations		
Medical observation [A] †	1/38 (2.63%)	0/43 (0%)
Metabolism and nutrition disorders		
Hyperkalaemia [A] †	0/38 (0%)	1/43 (2.33%)
Musculoskeletal and connective tissue disorders		
Fibromyalgia [A] †	0/38 (0%)	1/43 (2.33%)
Osteoporotic fracture [A] †	0/38 (0%)	1/43 (2.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Gastric cancer [A] †	0/38 (0%)	1/43 (2.33%)
Parathyroid tumour [A] †	0/38 (0%)	1/43 (2.33%)
Nervous system disorders		
Complex regional pain syndrome [A] †	0/38 (0%)	1/43 (2.33%)
Grand mal convulsion [A] †	1/38 (2.63%)	0/43 (0%)
Haemorrhagic stroke [A] †	1/38 (2.63%)	0/43 (0%)
Reversible posterior leukoencephalopathy syndrome [A] †	0/38 (0%)	1/43 (2.33%)
Psychiatric disorders		
Confusional state [A] †	1/38 (2.63%)	0/43 (0%)
Major depression [A] †	1/38 (2.63%)	0/43 (0%)
Renal and urinary disorders		
Haematuria [A] †	1/38 (2.63%)	0/43 (0%)
Reproductive system and breast disorders		
Metrorrhagia [A] †	0/38 (0%)	1/43 (2.33%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary oedema [A] †	1/38 (2.63%)	0/43 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.0)

Other Adverse Events

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

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	30/38 (78.95%)	38/43 (88.37%)
Blood and lymphatic system disorders		

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Anaemia [A] †	14/38 (36.84%)	14/43 (32.56%)
Endocrine disorders		
Hyperparathyroidism secondary [A] †	4/38 (10.53%)	6/43 (13.95%)
Hypothyroidism [A] †	4/38 (10.53%)	0/43 (0%)
Eye disorders		
Conjunctivitis [A] †	1/38 (2.63%)	3/43 (6.98%)
Eye pain [A] †	2/38 (5.26%)	1/43 (2.33%)
Gastrointestinal disorders		
Constipation [A] †	2/38 (5.26%)	0/43 (0%)
Diarrhoea [A] †	0/38 (0%)	4/43 (9.3%)
Dyspepsia [A] †	2/38 (5.26%)	2/43 (4.65%)
Nausea [A] †	2/38 (5.26%)	0/43 (0%)
Vomiting [A] †	2/38 (5.26%)	0/43 (0%)
General disorders		
Asthenia [A] †	7/38 (18.42%)	7/43 (16.28%)
Chills [A] †	3/38 (7.89%)	0/43 (0%)
Fatigue [A] †	6/38 (15.79%)	7/43 (16.28%)
Influenza like illness [A] †	6/38 (15.79%)	6/43 (13.95%)
Malaise [A] †	2/38 (5.26%)	1/43 (2.33%)
Pyrexia [A] †	5/38 (13.16%)	7/43 (16.28%)
Infections and infestations		
Oral herpes [A] †	2/38 (5.26%)	0/43 (0%)
Metabolism and nutrition disorders		

	Peginterferon Alfa-2a 135 Microgram (mcg)	Peginterferon Alfa-2a 90 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Anorexia [A] †	3/38 (7.89%)	3/43 (6.98%)
Hypocalcaemia [A] †	0/38 (0%)	3/43 (6.98%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	5/38 (13.16%)	1/43 (2.33%)
Myalgia [A] †	7/38 (18.42%)	8/43 (18.6%)
Pain in extremity [A] †	1/38 (2.63%)	3/43 (6.98%)
Nervous system disorders		
Dizziness [A] †	3/38 (7.89%)	2/43 (4.65%)
Headache [A] †	9/38 (23.68%)	13/43 (30.23%)
Psychiatric disorders		
Depression [A] †	1/38 (2.63%)	4/43 (9.3%)
Insomnia [A] †	4/38 (10.53%)	3/43 (6.98%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	3/38 (7.89%)	2/43 (4.65%)
Epistaxis [A] †	2/38 (5.26%)	1/43 (2.33%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	1/38 (2.63%)	4/43 (9.3%)
Dry skin [A] †	2/38 (5.26%)	0/43 (0%)
Pruritus [A] †	3/38 (7.89%)	2/43 (4.65%)
Vascular disorders		
Hypertension [A] †	5/38 (13.16%)	14/43 (32.56%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.0)

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:

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