Extended Treatment With PEG-Intron® and Rebetol® in Patients With Genotype 1 Chronic Hepatitis C and Slow Virologic Response (Study P03685)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00265395

First received: December 13, 2005
Last updated: October 7, 2015
Last verified: October 2015
History of Changes

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Purpose

This is a controlled, randomized, parallel-groups, open-label, multinational study designed to evaluate the efficacy and safety of PEG-Intron® (pegylated interferon alfa-2b) plus Rebetol® (ribavirin) in subjects with chronic hepatitis C. It is designed to evaluate whether 72 weeks of treatment with PEG-Intron plus Rebetol is more effective than 48 weeks of treatment in subjects with Genotype 1 chronic hepatitis C who exhibit a slow response to treatment.

Condition	Intervention	Phase
Hepatitis C, Chronic	Drug: Combination of pegylated interferon alfa-2b (PEG-Intron®) and ribavirin (Rebetol®) Drug: Combination of pegylated interferon alfa-2b and ribavirin	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Study to Assess Treatment With PEG-Intron® and Rebetol® in Naïve Patients With Genotype 1 Chronic Hepatitis C and Slow Virological Response

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Interferon Ribavirin Interferon Alfa-2a Interferon Alfa-2b Peginterferon Alfa-2b

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Sustained Virologic Response, Defined as a Plasma HCV-RNA (Hepatitis C Ribonucleic Acid) Level Below the LLQ (Lower Level of Quantitation) at 24 Weeks Post-treatment. [Time Frame: 48 or 72 weeks of treatment plus 24 weeks of follow-up.] [Designated as safety issue: No]

  LLQ = 30 IU/mL by reverse transcription polymerase chain reaction (RT-PCR) (Taqman Roche)

Enrollment:	1428
Study Start Date:	December 2004
Study Completion Date:	May 2008
Primary Completion Date:	May 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Standard therapy Slow responders (defined as being polymerase chain reaction [PCR] positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to stop treatment at Week 48.	Drug: Combination of pegylated interferon alfa-2b (PEG-Intron®) and ribavirin (Rebetol®) 1. Powder for injection in vial or Redipen (50, 80, 100, 120, and 150 microgram strengths), subcutaneous, dose of 1.5 micrograms/kg, weekly for 48 weeks 2. 200 mg capsules, oral, weight based dose of 800-1400 mg, daily for 48 weeks Other Names: • (a) SCH 54031; PEG-Intron; PegIntron; ViraferonPeg. • (b) SCH 18908; Rebetol; REBETOL.
Experimental: Extended therapy Slow responders (defined as being PCR positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to continue treatment to Week 72.	Drug: Combination of pegylated interferon alfa-2b and ribavirin 1. Powder for injection in vial or Redipen (50, 80, 100, 120, and 150 microgram strength), subcutaneous, dose of 1.5 micrograms/kg, weekly for 72 weeks. 2. 200 mg capsules, oral, weight based dose of 800-1400 mg, daily for 72 weeks Other Names: • (a) SCH 54031; PEG-Intron; PegIntron; ViraferonPeg. • (b) SCH 18908; Rebetol; REBETOL.

Eligibility

Ages Eligible for Study:	18 Years to 70 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Adult subjects aged 18 to 70 years, of either sex.
- Genotype-1 hepatitis C virus (HCV)-ribonucleic acid (RNA)-positive subjects.
- Subjects must be willing to give written informed consent and able to adhere to dosing and visit schedules.
- Confirmation of liver biopsy availability: Availability of a liver biopsy performed within 18 months prior to the Screen visit, with a pathology report confirming the histological diagnosis of chronic hepatitis or liver cirrhosis.
- Compensated liver disease with the following minimum hematological, biochemical, and serological criteria at the screen visit (WNL = within normal limits, ULN = Upper Limit Normal):
  - Hemoglobin values of equal or more than 12 g/dL for females and 13 g/dL for males.

- White blood cells (WBCs) equal to or more than 3,000/mm^3
- Neutrophil count equal to or more than 1,500/mm^3
- Platelet count equal to or more than 80,000/mm^3
- Direct bilirubin up to 10% above ULN is acceptable.
- Indirect bilirubin up to 10% above ULN is acceptable (unless non-hepatitis related factors such as Gilbert's disease explain an indirect bilirubin rise). In such cases indirect bilirubin should be less than or equal to 3.0 mg/dL (less than or equal to 51.3 µmol/L)
- Albumin up to 10% above ULN is acceptable.
- Serum creatinine up to 10% above ULN is acceptable.
- Alanine aminotransferase (ALT) level above ULN at Screen.

- At the Screen Visit, fasting glucose must be 70-140 mg/dL. Results between 116-140 mg/dL require repeat fasting glucose to be less than 140 mg/dL and HbA1C less than or equal to 8.5%. HbA1C must be less than or equal to 8.5% in diabetic subjects (whether on medication or diet controlled).
- Antinuclear antibodies (ANA) must be less than or equal to 1:320.
- Thyroid Stimulating Hormone (TSH) WNL whether in euthyroid subjects or subjects requiring medical treatment. (subjects requiring medication to maintain TSH levels within normal limits are eligible if all other inclusion/exclusion criteria are met).
- Confirmation by the principal investigator or a sub-investigator that sexually active females of childbearing potential are practicing adequate contraception.
- Female subjects cannot be pregnant or breastfeeding and must be either postmenopausal, surgically sterile or using 2 methods of birth control. While abstinence from sexual activity is the only certain method to prevent pregnancy, female patients of childbearing potential who are or who anticipate the possibility of becoming sexually active with a male partner must use a combination of the following 2 methods :
  - Contraceptive pill or intrauterine device (IUD) or depot hormonal preparation (ring, injection implant) and
  - A barrier method of contraception such as diaphragm, sponge with spermicide, condom, or a method of birth control considered acceptable by the study physician. Contraceptive measures will be reviewed with female subjects at each visit. Dual methods of contraception must be used for 1 month prior to the start of treatment and 6 months after treatment discontinuation.
- A serum pregnancy test obtained at Screen Visit prior to the initiation of treatment must be negative.
- Confirmation by the principal investigator or a sub-investigator that sexually active male subjects are practicing a method of contraception considered acceptable (vasectomy, condom plus spermicide, plus relationship with a female partner who practices an acceptable method of contraception). Contraception must be used during the treatment period and for seven months (or 6 months, according to local label) after the completion of therapy, including condom use by male subjects with pregnant partners.
- For subjects with a history of hypertension or diabetes, written clearance from an ophthalmologist has to be obtained prior to treatment start.

Exclusion Criteria:

- Pregnant women, women who plan to become pregnant, male subjects whose partner wants to become pregnant, and breastfeeding women.
- Previous treatment for chronic hepatitis C with an antiviral or immunomodulating agent or with some interferon or ribavirin product, whether alone or in combination.
- Subjects weighing over 125 kg.
- Suspected hypersensitivity to any interferon or ribavirin product.
- Participation in other clinical trial within 30 days prior to screen into this study.
- Coinfection with hepatitis B virus (HBV), human immunodeficiency virus (HIV), or both.
- Any cause of liver disease other than chronic hepatitis C, including but not limited to:
  - Hemochromatosis
  - Alpha-1 antitrypsin deficiency
  - Wilson's disease
  - Autoimmune hepatitis
  - Alcoholic liver disease
  - Non-alcoholic steatohepatitis (NASH)
  - Drug-related liver disease
- Active malignant disease or suspicion or history of malignant disease within five previous years (except for adequately treated basal cell carcinoma).
- Known coagulation diseases such as hemophilia; hemoglobin diseases (e.g. thalassemia).
- Known glucose 6-phosphate dehydrogenase (G6PD) deficiency
- Evidence of advanced liver disease such as history or presence of ascites, bleeding varices, or hepatic encephalopathy.
- Subjects with organ transplants, except for corneal or hair transplant.
- Any known preexisting medical condition that could interfere with the subject's participation in and completion of study, such as:

- Preexisting psychiatric condition, especially moderate to severe depression, or a history of severe psychiatric disorder, such as psychosis, suicidal ideation, or suicide attempts. Severe depression includes the following:
  - Hospitalization for depression
  - Electroconvulsive therapy for depression, or
  - Depression causing a prolonged absence from work or significantly altering daily functions.
- Subjects with mild depression may be considered for entry into the study provided that a pre-treatment assessment demonstrates that the subject's emotional status is clinically stable, in which case a management plan must be formulated for the subject; this management plan will become a part of the subject's medical record.
- Craniocerebral trauma which is not a concussion, or active seizure disorders requiring medication.
- Clinically significant electrocardiogram (ECG) abnormalities and/or cardiovascular dysfunction within 6 previous months (e.g., angina, congestive heart failure, recent myocardial infarction, or significant arrhythmia).
- Chronic lung disease (e.g., chronic obstructive lung disease)
- Poorly controlled diabetes mellitus
- Immune-mediated disease (e.g., inflammatory bowel disease [Crohn's disease, ulcerative colitis], idiopathic thrombocytopenic purpura, systemic lupus erythematosus, autoimmune hemolytic anemia, scleroderma, severe psoriasis)
- Clinical gout

- Subject is or was a substance abuser, such as alcohol (80 g/day or more), methadone, intravenous(IV), oral or inhaled drugs. To be considered for inclusion into the protocol, the subject must have abstained and agree to abstain from using any of the above for at least 6 months. Subjects treated with buprenorphine (Subutex) who have been stable for 6 months may be included.
- Cirrhotic subjects whose ultrasound confirms hepatocellular carcinoma.
- Any other condition that, in the investigator's opinion, could determine that subject's participation in the study is not indicated or could interfere with the subject's participation in and completion of study.
- Subjacent disease that potentially would require systematic administration of steroids
- Insulin dependent diabetes mellitus

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Buti M, Lurie Y, Zakharova NG, Blokhina NP, Horban A, Teuber G, Sarrazin C, Balciuniene L, Feinman SV, Faruqi R, Pedicone LD, Esteban R; SUCCESS Study Investigators. Randomized trial of peginterferon alfa-2b and ribavirin for 48 or 72 weeks in patients with hepatitis C virus genotype 1 and slow virologic response. Hepatology. 2010 Oct;52(4):1201-7. doi: 10.1002/hep.23816.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00265395 History of Changes
Other Study ID Numbers:	P03685 SUCCESS
Study First Received:	December 13, 2005
Results First Received:	May 15, 2009
Last Updated:	October 7, 2015
Health Authority:	Spain: Ethics Committee

Additional relevant MeSH terms:

Hepatitis	Interferon-alpha
Hepatitis A	Interferons
Hepatitis C	Peginterferon alfa-2b
Hepatitis C, Chronic	Ribavirin
Hepatitis, Chronic	Anti-Infective Agents
Digestive System Diseases	Antimetabolites
Enterovirus Infections	Antineoplastic Agents

Flaviviridae Infections
Hepatitis, Viral, Human
Liver Diseases
Picornaviridae Infections
RNA Virus Infections
Virus Diseases

Antiviral Agents
Immunologic Factors
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Therapeutic Uses

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Results First Received: May 15, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Drug: Combination of pegylated interferon alfa-2b (PEG-Intron®) and ribavirin (Rebetol®) Drug: Combination of pegylated interferon alfa-2b and ribavirin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
1428 patients enrolled; 159 patients qualified as slow responders per treatment week 12 and 24 protocol-specified eligibility criteria; 159 patients were randomized

Reporting Groups

	Description
Standard Therapy (48-week Treatment)	Slow responders (defined as being polymerase chain reaction [PCR] positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to stop treatment at Week 48.
Extended Therapy (72-week Treatment)	Slow responders (defined as being PCR positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to continue treatment to Week 72.

Participant Flow: Overall Study

	Standard Therapy (48-week Treatment)	Extended Therapy (72-week Treatment)
STARTED	**86**	**73**
COMPLETED	**78**	**56**
NOT COMPLETED	**8**	**17**
Adverse Event	**3**	**6**
Lost to Follow-up	**2**	**1**
Withdrawal by Subject	**1**	**6**
Protocol Violation	**2**	**2**
Lack of Efficacy	**0**	**1**
Administrative	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Standard Therapy (48-week Treatment)	Slow responders (defined as being polymerase chain reaction [PCR] positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to stop treatment at Week 48.
Extended Therapy (72-week Treatment)	Slow responders (defined as being PCR positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to continue treatment to Week 72.
Total	Total of all reporting groups

Baseline Measures

	Standard Therapy (48-week Treatment)	Extended Therapy (72-week Treatment)	Total
Number of Participants [units: participants]	**86**	**73**	**159**
Age [units: years]	**44.5 (9.9)**	**46.5 (11.6)**	**45.35 (10.79)**

Mean (Standard Deviation)			
Gender [units: participants]			
Female	**34**	**27**	**61**
Male	**52**	**46**	**98**

Outcome Measures

1. Primary: Sustained Virologic Response, Defined as a Plasma HCV-RNA (Hepatitis C Ribonucleic Acid) Level Below the LLQ (Lower Level of Quantitation) at 24 Weeks Post-treatment. [Time Frame: 48 or 72 weeks of treatment plus 24 weeks of follow-up.]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Sustained Virologic Response, Defined as a Plasma HCV-RNA (Hepatitis C Ribonucleic Acid) Level Below the LLQ (Lower Level of Quantitation) at 24 Weeks Post-treatment.
Measure Description	LLQ = 30 IU/mL by reverse transcription polymerase chain reaction (RT-PCR) (Taqman Roche)
Time Frame	48 or 72 weeks of treatment plus 24 weeks of follow-up.
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
According to the protocol, the efficacy analysis was carried out on all slow responders (ie, patients who had at least 2 log drop in HCV-RNA level at treatment week 12, and undetectable HCV-RNA at treatment week 24).

Reporting Groups

	Description
Standard Therapy (48-week Treatment)	Slow responders (defined as being polymerase chain reaction [PCR] positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to stop treatment at Week 48.
Extended Therapy (72-week Treatment)	Slow responders (defined as being PCR positive at Week 12 with at least 2 log reduction in viral load and PCR negative at Week 24) who are randomized at Week 48 to continue treatment to Week 72.

Measured Values

	Standard Therapy (48-week Treatment)	**Extended Therapy (72-week Treatment)**
Number of Participants Analyzed [units: participants]	**86**	**73**
Sustained Virologic Response, Defined as a Plasma HCV-RNA (Hepatitis C Ribonucleic Acid) Level Below the LLQ (Lower Level of Quantitation) at 24 Weeks Post-treatment. [units: Participants]	**37**	**35**

Statistical Analysis 1 for Sustained Virologic Response, Defined as a Plasma HCV-RNA (Hepatitis C Ribonucleic Acid) Level Below the LLQ (Lower Level of Quantitation) at 24 Weeks Post-treatment.

[1]	

Groups	All groups
Method [2]	Asymptotic Z-test
P Value [3]	0.6445
SVR Rate Difference [4]	-4.9
95% Confidence Interval	-20.4 to 10.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Standard Therapy (48-week Treatment)	No text entered.

Serious Adverse Events

	Standard Therapy (48-week Treatment)
Total, serious adverse events	
# participants affected / at risk	**93/1427 (6.52%)**
Blood and lymphatic system disorders	
ANAEMIA † 1	
# participants affected / at risk	**2/1427 (0.14%)**
# events	**2**
FEBRILE NEUTROPENIA † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**

PANCYTOPENIA † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
Cardiac disorders	
ATRIOVENTRICULAR BLOCK COMPLETE † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
ATRIOVENTRICULAR BLOCK SECOND DEGREE † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
BRADYCARDIA † 1	
# participants affected / at risk	**2/1427 (0.14%)**
# events	**2**
MYOCARDIAL INFARCTION † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
PALPITATIONS † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
PERICARDIAL EFFUSION † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
SINUS BRADYCARDIA † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
Ear and labyrinth disorders	
VERTIGO † 1	
# participants affected / at risk	**2/1427 (0.14%)**
# events	**2**
Endocrine disorders	
AUTOIMMUNE THYROIDITIS † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
HYPERTHYROIDISM † 1	
# participants affected / at risk	**2/1427 (0.14%)**
# events	**2**
HYPOTHYROIDISM † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
THYROIDITIS SUBACUTE † 1	
# participants affected / at risk	**1/1427 (0.07%)**
# events	**1**
Eye disorders	
RETINAL DETACHMENT † 1	

# participants affected / at risk	1/1427 (0.07%)
# events	1
RETINAL TEAR † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
VISUAL DISTURBANCE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Gastrointestinal disorders	
ABDOMINAL PAIN LOWER † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
COLITIS ULCERATIVE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CONSTIPATION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
GASTRITIS EROSIVE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INTESTINAL OBSTRUCTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INTUSSUSCEPTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
NAUSEA † 1	
# participants affected / at risk	4/1427 (0.28%)
# events	4
PANCREATITIS NECROTISING † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SMALL INTESTINAL OBSTRUCTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
VOLVULUS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
VOMITING † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
General disorders	
ASTHENIA † 1	
# participants affected / at risk	4/1427 (0.28%)

# events	5
PAIN † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
PYREXIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Hepatobiliary disorders	
CHOLECYSTITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CHOLECYSTITIS ACUTE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CHOLELITHIASIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
JAUNDICE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Immune system disorders	
HYPERSENSITIVITY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Infections and infestations	
ABSCESS LIMB † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
ABSCESS ORAL † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
APPENDICITIS † 1	
# participants affected / at risk	4/1427 (0.28%)
# events	4
CELLULITIS † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
CYTOMEGALOVIRUS INFECTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INFLUENZA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INJECTION SITE ABSCESS † 1	
# participants affected / at risk	1/1427 (0.07%)

# events	1
INJECTION SITE CELLULITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
LOBAR PNEUMONIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
ORCHITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
PNEUMONIA † 1	
# participants affected / at risk	4/1427 (0.28%)
# events	4
PULMONARY TUBERCULOSIS † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
PYELONEPHRITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SALMONELLOSIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SEPTIC SHOCK † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SYPHILIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
URINARY TRACT INFECTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Injury, poisoning and procedural complications	
ALCOHOL POISONING † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CLAVICLE FRACTURE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CONCUSSION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CONTUSION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
DISLOCATION OF VERTEBRA † 1	

# participants affected / at risk	1/1427 (0.07%)
# events	1
DRUG TOXICITY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INJURY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
MULTIPLE DRUG OVERDOSE INTENTIONAL † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
ROAD TRAFFIC ACCIDENT † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SCAPULA FRACTURE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
UPPER LIMB FRACTURE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Investigations	
ARTERIOGRAM † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HEART RATE INCREASED † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
PLATELET COUNT DECREASED † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
WHITE BLOOD CELL COUNT DECREASED † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Metabolism and nutrition disorders	
DIABETES MELLITUS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	2
HYPERCALCAEMIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HYPOGLYCAEMIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HYPONATRAEMIA † 1	
# participants affected / at risk	1/1427 (0.07%)

# events	1
Musculoskeletal and connective tissue disorders	
ARTHRALGIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
ARTHRITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
BACK PAIN † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
UNEQUAL LIMB LENGTH † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
CERVIX CARCINOMA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HEPATIC NEOPLASM MALIGNANT † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
PARATHYROID TUMOUR BENIGN † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
UTERINE LEIOMYOMA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Nervous system disorders	
CAROTID ARTERY DISSECTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CAROTID ARTERY OCCLUSION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CEREBRAL INFARCTION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
CONVULSION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
EPILEPSY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
GRAND MAL CONVULSION † 1	

# participants affected / at risk	2/1427 (0.14%)
# events	2
HEADACHE † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
MEMORY IMPAIRMENT † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
MIGRAINE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
NERVOUS SYSTEM DISORDER † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
PARKINSONISM † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SYNCOPE † 1	
# participants affected / at risk	3/1427 (0.21%)
# events	3
SYNCOPE VASOVAGAL † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
TREMOR † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Pregnancy, puerperium and perinatal conditions	
ABORTION SPONTANEOUS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Psychiatric disorders	
ALCOHOLISM † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
ANXIETY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
BIPOLAR DISORDER † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
COMPLETED SUICIDE † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
DELIRIUM † 1	
# participants affected / at risk	1/1427 (0.07%)

# events	1
DEPRESSION † 1	
# participants affected / at risk	4/1427 (0.28%)
# events	4
HALLUCINATION, AUDITORY † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HALLUCINATION, VISUAL † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HOMICIDAL IDEATION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
PANIC ATTACK † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
PARANOIA † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
PSYCHOTIC DISORDER † 1	
# participants affected / at risk	2/1427 (0.14%)
# events	2
SUICIDAL IDEATION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SUICIDE ATTEMPT † 1	
# participants affected / at risk	3/1427 (0.21%)
# events	3
Renal and urinary disorders	
OLIGURIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Reproductive system and breast disorders	
METRORRHAGIA † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Respiratory, thoracic and mediastinal disorders	
BRONCHITIS CHRONIC † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
DYSPNOEA EXERTIONAL † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
HAEMOPNEUMOTHORAX † 1	
# participants affected / at risk	1/1427 (0.07%)

# events	1
HAEMOPTYSIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
INTERSTITIAL LUNG DISEASE † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
OBLITERATIVE BRONCHIOLITIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Skin and subcutaneous tissue disorders	
ECZEMA NUMMULAR † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
SKIN LESION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Surgical and medical procedures	
ANAL FISSURE EXCISION † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1
Vascular disorders	
THROMBOSIS † 1	
# participants affected / at risk	1/1427 (0.07%)
# events	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Standard Therapy (48-week Treatment)	No text entered.

Other Adverse Events

	Standard Therapy (48-week Treatment)
Total, other (not including serious) adverse events	
# participants affected / at risk	1337/1427 (93.69%)
Blood and lymphatic system disorders	
ANAEMIA † 1	
# participants affected / at risk	197/1427 (13.81%)
# events	260
ERYTHROPENIA † 1	
# participants affected / at risk	74/1427 (5.19%)
# events	96
LEUKOPENIA † 1	
# participants affected / at risk	183/1427 (12.82%)
# events	268
NEUTROPENIA † 1	
# participants affected / at risk	281/1427 (19.69%)
# events	464
Gastrointestinal disorders	
ABDOMINAL PAIN UPPER † 1	
# participants affected / at risk	94/1427 (6.59%)
# events	112
DIARRHOEA † 1	
# participants affected / at risk	129/1427 (9.04%)
# events	152
DRY MOUTH † 1	
# participants affected / at risk	75/1427 (5.26%)
# events	75
NAUSEA † 1	
# participants affected / at risk	254/1427 (17.80%)
# events	301
General disorders	
ASTHENIA † 1	
# participants affected / at risk	402/1427 (28.17%)
# events	458
CHILLS † 1	
# participants affected / at risk	153/1427 (10.72%)
# events	204
FATIGUE † 1	
# participants affected / at risk	338/1427 (23.69%)
# events	412
INFLUENZA LIKE ILLNESS † 1	
# participants affected / at risk	599/1427 (41.98%)
# events	843

INJECTION SITE ERYTHEMA † 1	
# participants affected / at risk	**143/1427 (10.02%)**
# events	**152**
IRRITABILITY † 1	
# participants affected / at risk	**157/1427 (11.00%)**
# events	**169**
PYREXIA † 1	
# participants affected / at risk	**421/1427 (29.50%)**
# events	**834**
Investigations	
HAEMOGLOBIN DECREASED † 1	
# participants affected / at risk	**161/1427 (11.28%)**
# events	**215**
NEUTROPHIL COUNT DECREASED † 1	
# participants affected / at risk	**106/1427 (7.43%)**
# events	**171**
WEIGHT DECREASED † 1	
# participants affected / at risk	**150/1427 (10.51%)**
# events	**169**
WHITE BLOOD CELL COUNT DECREASED † 1	
# participants affected / at risk	**77/1427 (5.40%)**
# events	**112**
Metabolism and nutrition disorders	
ANOREXIA † 1	
# participants affected / at risk	**156/1427 (10.93%)**
# events	**160**
DECREASED APPETITE † 1	
# participants affected / at risk	**103/1427 (7.22%)**
# events	**107**
Musculoskeletal and connective tissue disorders	
ARTHRALGIA † 1	
# participants affected / at risk	**195/1427 (13.67%)**
# events	**235**
BACK PAIN † 1	
# participants affected / at risk	**91/1427 (6.38%)**
# events	**106**
MYALGIA † 1	
# participants affected / at risk	**274/1427 (19.20%)**
# events	**417**
Nervous system disorders	
DISTURBANCE IN ATTENTION † 1	
# participants affected / at risk	**77/1427 (5.40%)**
# events	**81**
DIZZINESS † 1	

# participants affected / at risk	115/1427 (8.06%)
# events	128
HEADACHE † 1	
# participants affected / at risk	408/1427 (28.59%)
# events	569
Psychiatric disorders	
DEPRESSION † 1	
# participants affected / at risk	139/1427 (9.74%)
# events	156
INSOMNIA † 1	
# participants affected / at risk	178/1427 (12.47%)
# events	194
Respiratory, thoracic and mediastinal disorders	
COUGH † 1	
# participants affected / at risk	195/1427 (13.67%)
# events	213
DYSPNOEA † 1	
# participants affected / at risk	111/1427 (7.78%)
# events	124
Skin and subcutaneous tissue disorders	
ALOPECIA † 1	
# participants affected / at risk	318/1427 (22.28%)
# events	328
DRY SKIN † 1	
# participants affected / at risk	188/1427 (13.17%)
# events	199
PRURITUS † 1	
# participants affected / at risk	267/1427 (18.71%)
# events	290
RASH † 1	
# participants affected / at risk	177/1427 (12.40%)
# events	211

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 10.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is:

- [x] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Buti M, Lurie Y, Zakharova NG, Blokhina NP, Horban A, Teuber G, Sarrazin C, Balciuniene L, Feinman SV, Faruqi R, Pedicone LD, Esteban R; SUCCESS Study Investigators. Randomized trial of peginterferon alfa-2b and ribavirin for 48 or 72 weeks in patients with hepatitis C virus genotype 1 and slow virologic response. Hepatology. 2010 Oct;52(4):1201-7. doi: 10.1002/hep.23816.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00265395 History of Changes
Other Study ID Numbers:	P03685 SUCCESS
Study First Received:	December 13, 2005
Results First Received:	May 15, 2009
Last Updated:	October 7, 2015
Health Authority:	Spain: Ethics Committee

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For Patients and Families | For Researchers | For Study Record Managers

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