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Study of Response in Chronic Hepatitis C (CHC) Participants Genotype 1 With Insulin Resistance and Prolonged Treatment Duration in Late Responders (P04823/MK-4031-303)

This study has been terminated.
(Slow Enrollment)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00493805

First received: June 25, 2007
Last updated: November 2, 2015
Last verified: November 2015
History of Changes

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Purpose

This is a Phase 3b/4, prospective, open-label, randomized, multicenter study of peginterferon alfa-2b plus ribavirin in participants with chronic hepatitis C, genotype 1. The study consists of two parts: (1) a noninterventional arm (HOMA IR <= 2) and (2) an interventional arm (HOMA IR > 2), where HOMA IR is the insulin resistance index for the participants calculated by fasting insulin (uU/mL) x [fasting glucose (mmol/L)/22.5]. Participants in the noninterventional arm are treated according to the European labeling and response rates are evaluated at Month 1 (optional), 3, 6, 12, and follow up. Participants in the interventional arm are treated with PEG-Intron 1.5 ug/kg (subcutaneous) once weekly plus weight-based REBETOL 800-1400 mg (oral capsules) daily for a variable period depending on their response at Week 12: (1) HCV-RNA positive with < 2-log drop in viral load, treatment will be discontinued; (2) HCV-RNA positive with >= 2-log drop in viral load; participants will be randomized (1:1) to Group A (stop treatment at Week 48) or Group B (stop treatment at Week 72); and (3) HCV-RNA negative, treatment will be changed to be according to the European labeling and response rates will be evaluated at Month 6, 12, and follow up. All participants will go on with their treatment after Week 12 until the results of the HCV polymerase chain reaction (PCR) are available (maximum of 4 weeks).

Condition	Intervention	Phase
Hepatitis C, Chronic Insulin Resistance	Drug: Combination of pegylated interferon alfa-2b and ribavirin	Phase 4

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

Official Title: Study to Evaluate Response Rates in Chronic Hepatitis C (CHC) Patients Genotype 1 With Insulin Resistance and to Assess Prolonged Treatment Duration in Late Virological Responders

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Insulin Interferon Insulin human 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:

- Early Virological Response in Participants With and Without Insulin Resistance [Time Frame: At Week 12 (after start of therapy)] [Designated as safety issue: No]

  Early Virological Response (EVR) defined as HCV PCR at Week 12 either negative or at least 2 log units less than baseline in participants with and without insulin resistance.

Secondary Outcome Measures:

- Sustained Virological Response (PCR 24 Weeks After End of Treatment) [Time Frame: Up to 24 weeks following 48 or 72 weeks of therapy] [Designated as safety issue: No]

  Sustained virological response (SVR) was defined as undetectable HCV RNA in serum at the end of follow-up (24 weeks after end of therapy) according to a polymerase chain reaction (PCR) assay.

Enrollment:	59
Study Start Date:	April 2007
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Interventional Study arm (with insulin resistance) HOMA IR (homeostasis model assessment-estimated insulin resistance) of > 2 These participants received PEG-Intron 1.5 µg /kg subcutaneously (SC) once weekly plus weight based Rebetol 800-1400 mg by mouth (PO) administered twice daily (BID) for a variable period depending on their response to treatment.	Drug: Combination of pegylated interferon alfa-2b and ribavirin 1. Powder for injection in Redipen (50, 80, 100, 120, and 150 microgram strengths), subcutaneous, dose of 1.5 micrograms/kg, weekly for 12 weeks, then up to 4 weeks until HCV PCR results are available, and then for another 36 weeks(Group A) or 60 weeks (Group B) postrandomization. 2. 200 mg capsules, oral, weight based dose of 800-1400 mg, daily for up to 12 weeks, then up to 4 weeks until HCV PCR results are available, and then for another 36 weeks (Group A) or 60 weeks (Group B) postrandomization Other Names: • (a) SCH 54031, PEG-Intron • (b) SCH 18908, Rebetol
Experimental: Non interventional study arm (without insulin resistance) HOMA IR <= 2 These participants received PEG-Intron 1.5 µg /kg subcutaneously (SC) once weekly plus weight based Rebetol 800-1400 mg PO administered twice daily (BID) for 48 weeks. (Participants are treated according to European labeling).	Drug: Combination of pegylated interferon alfa-2b and ribavirin 1. Powder for injection in 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 • (b) SCH 18908, Rebetol

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- male and female participants with newly diagnosed chronic hepatitis C
- age 18-65
- HCV-RNA positive in serum as measured by PCR
- Genotype 1
- ALT levels according to European labeling
- in women of child-bearing age, pregnancy must be excluded prior to entry into the study, and the use of a safe contraceptive device must be documented; sexually active male participants must practice a method of contraception considered acceptable (vasectomy, condom plus spermicide, plus relationship with a female partner who practices an acceptable method of contraception)
- Lab parameters:
  - Hb: >=12 g/dL (women) or >= 13 g/dL (men)
  - leukocytes >= 3,000/µL
  - thrombocytes >= 100,000/µL
  - PT/PTT/coagulation must be within normal limits or clinically acceptable to the investigator/sponsor
  - Albumin must be within normal limits or clinically acceptable to the investigator/sponsor
  - creatinine must be within normal limits or clinically acceptable to the investigator/sponsor
  - uric acid must be within normal limits or clinically acceptable to the investigator/sponsor
- antinuclear antibodies <= 1:160
- signed informed consent

Exclusion Criteria:

- refusal by women of child-bearing age or by sexually active participants to use a safe contraceptive
- breast-feeding women
- cirrhosis stage B and C according to Child-Pugh
- signs of decompensated liver disease
- confirmed co-infection with HIV or HBV
- existing psychiatric comorbidity
- alcohol abuse
- active malignant disease or suspicion or history of malignant disease within 5 previous years (except for adequately treated basal cell carcinoma)
- existing psoriasis or other dermatological disorder
- treatment with a study drug within the last 30 days
- any uncontrolled underlying medical conditions
- clinically significant ECG abnormalities and/or significant cardiovascular dysfunction within the last 6 months. In case of other suspected heart disease, a cardiological examination is required.
- any liver disorder of other genesis than the study indication (with regard to elevated iron levels, only participants with manifest hemochromatosis are excluded)
- autoimmune disorder (except LKM-positive participants).

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00493805 History of Changes
Other Study ID Numbers:	P04823 EudraCT number:2006-000757-21
Study First Received:	June 25, 2007
Results First Received:	October 27, 2010
Last Updated:	November 2, 2015
Health Authority:	Austria: Agency for Health and Food Safety

Keywords provided by Merck Sharp & Dohme Corp.:
homeostasis model assessment of insulin resistance

Additional relevant MeSH terms:

Hepatitis	RNA Virus Infections
Hepatitis A	Virus Diseases
Hepatitis C	Insulin
Hepatitis C, Chronic	Insulin, Globin Zinc
Hepatitis, Chronic	Interferon-alpha
Insulin Resistance	Interferons
Digestive System Diseases	Peginterferon alfa-2b
Enterovirus Infections	Ribavirin
Flaviviridae Infections	Anti-Infective Agents
Glucose Metabolism Disorders	Antimetabolites
Hepatitis, Viral, Human	Antineoplastic Agents
Hyperinsulinism	Antiviral Agents
Liver Diseases	Hypoglycemic Agents
Metabolic Diseases	Immunologic Factors
Picornaviridae Infections	Molecular Mechanisms of Pharmacological Action

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Results First Received: October 27, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Hepatitis C, Chronic Insulin Resistance
Intervention:	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
No text entered.

Reporting Groups

	Description
Non Interventional Arm HOMA IR <= 2	Participants in the non-interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) for 48 weeks together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 48 weeks (according to European labeling). Followed by a 24-week follow up period after end of treatment.
Interventional Arm HOMA IR > 2	Participants in the interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 12-16 weeks until their HCV polymerase chain reaction (PCR) results are available at Week 12. At Week 12, participants with >=2 log decrease of HCV RNA were randomized to continue either for another 36 weeks (Group A- a total of 48 weeks therapy) OR for another 60 weeks (Group B- a total of 72 weeks of therapy) with a 24-week follow up. Randomization was done between Day 1 Week 17 and Day 1 Week 25.

Participant Flow: Overall Study

	Non Interventional Arm HOMA IR <= 2	Interventional Arm HOMA IR > 2
STARTED	**17**	**42**
COMPLETED	**17**	**42**
NOT COMPLETED	**0**	**0**

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
Total for Interventional Arm and Non Interventional Arm	No text entered.

Baseline Measures

	Total for Interventional Arm and Non Interventional Arm
Number of Participants [units: participants]	**59**
Age, Customized [units: Participants]	
Between 18 and 65 years	**59**
Gender, Customized [units: Participants]	
Male	**35**

Female	**24**

Outcome Measures

Hide All Outcome Measures

1. Primary: Early Virological Response in Participants With and Without Insulin Resistance [Time Frame: At Week 12 (after start of therapy)]

Measure Type	Primary
Measure Title	Early Virological Response in Participants With and Without Insulin Resistance
Measure Description	Early Virological Response (EVR) defined as HCV PCR at Week 12 either negative or at least 2 log units less than baseline in participants with and without insulin resistance.
Time Frame	At Week 12 (after start of therapy)
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.
Interventional arm: At baseline, PCR measurements for 38 out of 42 participants were available. Non Interventional arm: At baseline, PCR measurements for 15 out of 17 participants were available.

Reporting Groups

	Description
Non Interventional Arm HOMA IR <= 2	Participants in the non-interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) for 48 weeks together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 48 weeks (according to European labeling). Followed by a 24-week follow up period after end of treatment.
Interventional Arm HOMA IR > 2	Participants in the interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 12-16 weeks until their HCV polymerase chain reaction (PCR) results are available at Week 12. At Week 12, participants with >=2 log decrease of HCV RNA were randomized to continue either for another 36 weeks (Group A- a total of 48 weeks therapy) OR for another 60 weeks (Group B- a total of 72 weeks of therapy) with a 24-week follow up. Randomization was done between Day 1 Week 17 and Day 1 Week 25.

Measured Values

	Non Interventional Arm HOMA IR <= 2	**Interventional Arm HOMA IR > 2**
Number of Participants Analyzed [units: participants]	**15**	**38**
Early Virological Response in Participants With and Without Insulin Resistance [units: Participants]	**10**	**24**

No statistical analysis provided for Early Virological Response in Participants With and Without Insulin Resistance

2. Secondary: Sustained Virological Response (PCR 24 Weeks After End of Treatment) [Time Frame: Up to 24 weeks following 48 or 72 weeks of therapy]

Measure Type	Secondary
Measure Title	Sustained Virological Response (PCR 24 Weeks After End of Treatment)
Measure Description	Sustained virological response (SVR) was defined as undetectable HCV RNA in serum at the end of follow-up (24 weeks after end of therapy) according to a polymerase chain reaction (PCR) assay.
Time Frame	Up to 24 weeks following 48 or 72 weeks of therapy
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.
Information on PCR was available for 7 participants in the non interventional study arm and 11 participants in the interventional study arm.

Reporting Groups

	Description
Non Interventional Arm HOMA IR <= 2	Participants in the non-interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) for 48 weeks together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 48 weeks (according to European labeling). Followed by a 24-week follow up period after end of treatment.
Interventional Arm HOMA IR > 2	Participants in the interventional arm received PegIntron at a dose of 1.5 µg /kg based on the subject's body weight at baseline visit; administrated once weekly, subcutaneously (SC) together with Rebetol at a dose of 800-1400 mg based on the subject's body weight at baseline visit; administered twice daily (BID), by mouth (PO) for 12-16 weeks until their HCV polymerase chain reaction (PCR) results are available at Week 12. At Week 12, participants with >=2 log decrease of HCV RNA were randomized to continue either for another 36 weeks (Group A- a total of 48 weeks therapy) OR for another 60 weeks (Group B- a total of 72 weeks of therapy) with a 24-week follow up. Randomization was done between Day 1 Week 17 and Day 1 Week 25.

Measured Values

	Non Interventional Arm HOMA IR <= 2	**Interventional Arm HOMA IR > 2**
Number of Participants Analyzed [units: participants]	**7**	**11**
Sustained Virological Response (PCR 24 Weeks After End of Treatment) [units: Participants]	**1**	**3**

No statistical analysis provided for Sustained Virological Response (PCR 24 Weeks After End of Treatment)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Non Interventional Arm HOMA IR <=2	No text entered.
Interventional Arm HOMA IR >2	No text entered.

Serious Adverse Events

	Non Interventional Arm HOMA IR <=2	Interventional Arm HOMA IR >2
Total, serious adverse events		
# participants affected / at risk	**3/17 (17.65%)**	**4/42 (9.52%)**
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**
# events	**1**	**0**
NEUTROPENIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**1/42 (2.38%)**
# events	**1**	**1**
Cardiac disorders		
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**0/17 (0.00%)**	**1/42 (2.38%)**
# events	**0**	**1**
Endocrine disorders		
HYPERTHYROIDISM † 1		
# participants affected / at risk	**0/17 (0.00%)**	**1/42 (2.38%)**
# events	**0**	**1**
General disorders		
NON-CARDIAC CHEST PAIN † 1		
# participants affected / at risk	**0/17 (0.00%)**	**1/42 (2.38%)**
# events	**0**	**1**
Infections and infestations		
GASTROENTERITIS † 1		
# participants affected / at risk	**0/17 (0.00%)**	**1/42 (2.38%)**
# events	**0**	**1**
Psychiatric disorders		
SUICIDE ATTEMPT † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.1

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
Non Interventional Arm HOMA IR <=2	No text entered.
Interventional Arm HOMA IR >2	No text entered.

Other Adverse Events

	Non Interventional Arm HOMA IR <=2	Interventional Arm HOMA IR >2
Total, other (not including serious) adverse events		
# participants affected / at risk	**15/17 (88.24%)**	**37/42 (88.10%)**
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**10/42 (23.81%)**
# events	**4**	**28**
HAEMOGLOBINAEMIA † 1		
# participants affected / at risk	**0/17 (0.00%)**	**3/42 (7.14%)**
# events	**0**	**9**
LEUKOPENIA † 1		
# participants affected / at risk	**8/17 (47.06%)**	**13/42 (30.95%)**
# events	**14**	**34**
NEUTROPENIA † 1		
# participants affected / at risk	**6/17 (35.29%)**	**12/42 (28.57%)**
# events	**13**	**26**
THROMBOCYTOPENIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**2/42 (4.76%)**
# events	**1**	**10**
Cardiac disorders		
TACHYCARDIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**

# events	1	0
Endocrine disorders		
HYPOTHYROIDISM † 1		
# participants affected / at risk	0/17 (0.00%)	3/42 (7.14%)
# events	0	3
Eye disorders		
VISUAL ACUITY REDUCED † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
Gastrointestinal disorders		
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	0/17 (0.00%)	5/42 (11.90%)
# events	0	6
CHAPPED LIPS † 1		
# participants affected / at risk	0/17 (0.00%)	3/42 (7.14%)
# events	0	4
CHEILITIS † 1		
# participants affected / at risk	0/17 (0.00%)	5/42 (11.90%)
# events	0	5
CONSTIPATION † 1		
# participants affected / at risk	1/17 (5.88%)	2/42 (4.76%)
# events	1	2
DIARRHOEA † 1		
# participants affected / at risk	2/17 (11.76%)	3/42 (7.14%)
# events	2	3
DRY MOUTH † 1		
# participants affected / at risk	0/17 (0.00%)	3/42 (7.14%)
# events	0	3
GINGIVAL BLEEDING † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
NAUSEA † 1		
# participants affected / at risk	3/17 (17.65%)	8/42 (19.05%)
# events	4	8
ORAL PAIN † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
VOMITING † 1		
# participants affected / at risk	0/17 (0.00%)	5/42 (11.90%)
# events	0	5
General disorders		
CHEST PAIN † 1		
# participants affected / at risk	2/17 (11.76%)	1/42 (2.38%)
# events	2	1
† 1		

FATIGUE		
# participants affected / at risk	**2/17 (11.76%)**	**8/42 (19.05%)**
# events	**2**	**8**
FEELING COLD † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**
# events	**1**	**0**
INFLUENZA LIKE ILLNESS † 1		
# participants affected / at risk	**5/17 (29.41%)**	**13/42 (30.95%)**
# events	**5**	**14**
PAIN † 1		
# participants affected / at risk	**1/17 (5.88%)**	**1/42 (2.38%)**
# events	**1**	**1**
PYREXIA † 1		
# participants affected / at risk	**3/17 (17.65%)**	**7/42 (16.67%)**
# events	**3**	**12**
Metabolism and nutrition disorders		
DECREASED APPETITE † 1		
# participants affected / at risk	**2/17 (11.76%)**	**4/42 (9.52%)**
# events	**2**	**4**
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**3/42 (7.14%)**
# events	**1**	**3**
MYALGIA † 1		
# participants affected / at risk	**3/17 (17.65%)**	**4/42 (9.52%)**
# events	**3**	**4**
Nervous system disorders		
DYSGEUSIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**
# events	**1**	**0**
HEADACHE † 1		
# participants affected / at risk	**3/17 (17.65%)**	**14/42 (33.33%)**
# events	**3**	**15**
HYPOTONIA † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**
# events	**1**	**0**
SYNCOPE † 1		
# participants affected / at risk	**2/17 (11.76%)**	**0/42 (0.00%)**
# events	**2**	**0**
Psychiatric disorders		
DEPRESSION † 1		
# participants affected / at risk	**4/17 (23.53%)**	**5/42 (11.90%)**
# events	**6**	**5**
DYSTHYMIC DISORDER † 1		
# participants affected / at risk	**1/17 (5.88%)**	**0/42 (0.00%)**

# events	1	0
SLEEP DISORDER † 1		
# participants affected / at risk	3/17 (17.65%)	6/42 (14.29%)
# events	3	7
Respiratory, thoracic and mediastinal disorders		
ASTHMA † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
COUGH † 1		
# participants affected / at risk	2/17 (11.76%)	1/42 (2.38%)
# events	2	1
DRY THROAT † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
DYSPNOEA † 1		
# participants affected / at risk	1/17 (5.88%)	2/42 (4.76%)
# events	1	2
OROPHARYNGEAL PAIN † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
ALOPECIA † 1		
# participants affected / at risk	4/17 (23.53%)	6/42 (14.29%)
# events	6	6
DRY SKIN † 1		
# participants affected / at risk	1/17 (5.88%)	6/42 (14.29%)
# events	1	6
ERYTHEMA † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
NEURODERMATITIS † 1		
# participants affected / at risk	1/17 (5.88%)	0/42 (0.00%)
# events	1	0
PRURITUS † 1		
# participants affected / at risk	4/17 (23.53%)	11/42 (26.19%)
# events	5	12
RASH † 1		
# participants affected / at risk	1/17 (5.88%)	6/42 (14.29%)
# events	1	6
URTICARIA † 1		
# participants affected / at risk	2/17 (11.76%)	1/42 (2.38%)
# events	2	1
Vascular disorders		
POOR PERIPHERAL CIRCULATION † 1		

# participants affected / at risk	2/17 (11.76%)	0/42 (0.00%)
# events	2	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

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 **NOT** 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.

Results Point of Contact:

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

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00493805 History of Changes
Other Study ID Numbers: P04823
EudraCT number:2006-000757-21
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