A Study of Vaniprevir (MK-7009) in Participants With Chronic Hepatitis C Infection After Participation in Other Vaniprevir Studies (MK-7009-028)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00943761

First received: July 21, 2009
Last updated: September 1, 2015
Last verified: September 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study will provide vaniprevir 600 mg or 300 mg twice daily in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) to participants with chronic hepatitis C virus (HCV) infection who did not achieve viral eradication while participating in a prior vaniprevir clinical trial (MK-7009-004, NCT00518622; MK-7009-007, NCT00704405; MK-7009-009, NCT00704184; and MK-7009-029, NCT00954993).

Condition	Intervention	Phase
Hepatitis C, Chronic	Drug: Vaniprevir 600 mg b.i.d. Drug: Vaniprevir 300 mg b.i.d. Drug: Pegylated interferon Drug: Ribavirin	Phase 2

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

Official Title: A Phase II Open Label Study of MK-7009 Administered Concomitantly With Pegylated Interferon Alfa-2a and Ribavirin to Patients With Chronic Hepatitis C Infection After Participation in Other MK-7009 Clinical Trials

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Interferon Ribavirin

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants Who Experienced an Adverse Event [Time Frame: up to 72 weeks] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.

- Number of Participants Who Experienced a Serious Adverse Event [Time Frame: up to 72 weeks] [Designated as safety issue: Yes]

  Serious adverse event is defined as any adverse drug or biologic or device experience occurring at any dose resulting in death, was life-threatening, was persistent or caused significant disability/incapacity, required in-patient hospitalization or prolonged hospitalization, was a congenital anomaly or birth defect, was a cancer, or was an overdose.

- Number of Participants Who Discontinued Study Treatment Due to an Adverse Event [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.

- Percentage of Participants Who Achieved Sustained Viral Response 24 Weeks After the End of Treatment (SVR24) [Time Frame: 72 weeks] [Designated as safety issue: No]

  SVR24 is defined as undetectable hepatitis C virus ribonucleic acid (HCV RNA) 24 weeks after the end of vaniprevir study therapy. HCV RNA plasma levels were assessed using the Roche COBAS Taqman assay (or equivalent) with the limit of quantification (LoQ) of at least 25 IU/mL and the limit of detection (LoD) of at least 10 IU/mL.

Enrollment:	45
Study Start Date:	October 2009
Study Completion Date:	May 2013
Primary Completion Date:	May 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Vaniprevir 300 mg b.i.d. + peg-IFN + RBV Participants received vaniprevir 300 mg twice daily (b.i.d.) in combination peg-IFN 180 mcg weekly and ribavirin (1000 or 1200 mg) administered as a divided dose twice daily.	Drug: Vaniprevir 300 mg b.i.d. Oral capsules containing 150 mg vaniprevir, two in the morning and two in the evening, for 48 weeks Drug: Pegylated interferon Prefilled syringe containing 180 µg/0.5 mL peg-IFN, for weekly subcutaneous injection, for 48 weeks Other Name: PEGASYS™ Drug: Ribavirin Oral tablets containing 200 mg RBV, 5 or 6 tablets, dosage based on the participant's weight (<75 kg or ≥75 kg, respectively), for 48 weeks Other Name: COPEGUS™
Experimental: Vaniprevir 600 mg b.i.d. + peg-IFN + RBV Participants received vaniprevir 600 mg b.i.d. in combination peg-IFN 180 mcg weekly and ribavirin (1000 or 1200 mg) administered as a divided dose twice daily.	Drug: Vaniprevir 600 mg b.i.d. Oral capsules containing 150 mg vaniprevir, four in the morning and four in the evening, for 48 weeks Drug: Pegylated interferon Prefilled syringe containing 180 µg/0.5 mL peg-IFN, for weekly subcutaneous injection, for 48 weeks Other Name: PEGASYS™ Drug: Ribavirin Oral tablets containing 200 mg RBV, 5 or 6 tablets, dosage based on the participant's weight (<75 kg or ≥75 kg, respectively), for 48 weeks Other Name: COPEGUS™

Eligibility

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

Criteria

Inclusion criteria:

- Participant has participated in a prior vaniprevir clinical trial
- Participant agrees to use acceptable birth control method during treatment

Exclusion criteria:

- More than one year has passed since the participant was determined to be eligible for enrollment in protocol 028
- Participant discontinued vaniprevir and/or peg-IFN and/or RBV in the prior study due to a safety or tolerability issue
- Participant received any investigational therapy for HCV after participating in the prior study

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00943761

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00943761 History of Changes
Other Study ID Numbers:	**7009-028** 2009_615 2009-013053-15
Study First Received:	July 21, 2009
Results First Received:	September 26, 2014
Last Updated:	September 1, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
hepatitis C

Additional relevant MeSH terms:

Hepatitis	RNA Virus Infections
Hepatitis A	Virus Diseases
Hepatitis C	Interferons
Hepatitis C, Chronic	Ribavirin
Hepatitis, Chronic	Anti-Infective Agents
Digestive System Diseases	Antimetabolites
Enterovirus Infections	Antineoplastic Agents
Flaviviridae Infections	Antiviral Agents
Hepatitis, Viral, Human	Molecular Mechanisms of Pharmacological Action
Liver Diseases	Pharmacologic Actions
Picornaviridae Infections	Therapeutic Uses

ClinicalTrials.gov processed this record on March 30, 2016

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Results First Received: September 26, 2014

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Drug: Vaniprevir 600 mg b.i.d. Drug: Vaniprevir 300 mg b.i.d. Drug: Pegylated interferon Drug: 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
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination pegylated interferon (peg-IFN) 180 mcg weekly and ribavirin (RBV) 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.

Participant Flow: Overall Study

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV
STARTED	**21**	**24**
COMPLETED	**17**	**23**
NOT COMPLETED	**4**	**1**
Lost to Follow-up	**2**	**0**
Withdrawal by Subject	**2**	**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
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.
Total	Total of all reporting groups

Baseline Measures

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Total
Number of Participants [units: participants]	**21**	**24**	**45**
Age [units: Years] Mean (Standard Deviation)	**52.5 (7.4)**	**48.1 (8.4)**	**50.2 (8.1)**
Gender [units: Participants]			
Female	**7**	**4**	**11**
Male	**14**	**20**	**34**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Experienced an Adverse Event [Time Frame: up to 72 weeks]

Measure Type	Primary
Measure Title	Number of Participants Who Experienced an Adverse Event
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.
Time Frame	up to 72 weeks
Safety Issue	Yes

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.
All participants as treated population consists of all participants who received at least one dose of study treatment.

Reporting Groups

	Description
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.

Measured Values

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	**Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV**
Number of Participants Analyzed [units: participants]	**21**	**24**
Number of Participants Who Experienced an Adverse Event [units: Participants]	**21**	**23**

No statistical analysis provided for Number of Participants Who Experienced an Adverse Event

2. Primary: Number of Participants Who Experienced a Serious Adverse Event [Time Frame: up to 72 weeks]

Measure Type	Primary
Measure Title	Number of Participants Who Experienced a Serious Adverse Event
Measure Description	Serious adverse event is defined as any adverse drug or biologic or device experience occurring at any dose resulting in death, was life-threatening, was persistent or caused significant disability/incapacity, required in-patient hospitalization or prolonged hospitalization, was a congenital anomaly or birth defect, was a cancer, or was an overdose.
Time Frame	up to 72 weeks
Safety Issue	Yes

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.
All participants as treated population consists of all participants who received at least one dose of study treatment.

Reporting Groups

	Description
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.

Measured Values

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	**Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV**
Number of Participants Analyzed [units: participants]	**21**	**24**
Number of Participants Who Experienced a Serious Adverse Event [units: Participants]	**4**	**1**

No statistical analysis provided for Number of Participants Who Experienced a Serious Adverse Event

3. Primary: Number of Participants Who Discontinued Study Treatment Due to an Adverse Event [Time Frame: 48 weeks]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Study Treatment Due to an Adverse Event
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.
Time Frame	48 weeks
Safety Issue	Yes

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.
All participants as treated population consists of all participants who received at least one dose of study treatment.

Reporting Groups

	Description
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.

Measured Values

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV
Number of Participants Analyzed [units: participants]	**21**	**24**
Number of Participants Who Discontinued Study Treatment Due to an Adverse Event [units: Participants]	**2**	**1**

No statistical analysis provided for Number of Participants Who Discontinued Study Treatment Due to an Adverse Event

4. Primary: Percentage of Participants Who Achieved Sustained Viral Response 24 Weeks After the End of Treatment (SVR24) [Time Frame: 72 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants Who Achieved Sustained Viral Response 24 Weeks After the End of Treatment (SVR24)
Measure Description	SVR24 is defined as undetectable hepatitis C virus ribonucleic acid (HCV RNA) 24 weeks after the end of vaniprevir study therapy. HCV RNA plasma levels were assessed using the Roche COBAS Taqman assay (or equivalent) with the limit of quantification (LoQ) of at least 25 IU/mL and the limit of detection (LoD) of at least 10 IU/mL.
Time Frame	72 weeks
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.
Population includes only a subset of participants previously treated with placebo + peg-IFN + RBV in a vaniprevir study and excludes participants for failure to receive >=1 dose of study drug, lack of any post-allocation endpoint data subsequent to >=1 dose of study drug, lack of baseline data, or missing data due to discontinuation from the study

Reporting Groups

	Description
Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and ribavirin 1000 or 1200 mg administered as a divided dose twice daily.

Measured Values

	Vaniprevir 300 mg b.i.d. + Peg-IFN + RBV	Vaniprevir 600 mg b.i.d. + Peg-IFN + RBV
Number of Participants Analyzed [units: participants]	**18**	**17**
Percentage of Participants Who Achieved Sustained Viral Response 24 Weeks After the End of Treatment (SVR24) [units: Percentage of participants] Number (95% Confidence Interval)	**66.7 (41.0 to 86.7)**	**70.6 (44.0 to 89.7)**

No statistical analysis provided for Percentage of Participants Who Achieved Sustained Viral Response 24 Weeks After the End of Treatment (SVR24)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 72 weeks
Additional Description	No text entered.

Reporting Groups

	Description
Vaniprevir 300 mg Bid + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg Bid + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.

Serious Adverse Events

	Vaniprevir 300 mg Bid + Peg-IFN + RBV	Vaniprevir 600 mg Bid + Peg-IFN + RBV
Total, serious adverse events		
# participants affected / at risk	**4/21 (19.05%)**	**1/24 (4.17%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/21 (4.76%)**	**0/24 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	**1/21 (4.76%)**	**0/24 (0.00%)**
# events	**1**	**0**
Diarrhoea † 1		
# participants affected / at risk	**1/21 (4.76%)**	**0/24 (0.00%)**
# events	**1**	**0**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**1/21 (4.76%)**	**0/24 (0.00%)**
# events	**1**	**0**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**1/21 (4.76%)**	**0/24 (0.00%)**
# events	**1**	**0**
Musculoskeletal and connective tissue disorders		
Musculoskeletal chest pain † 1		
# participants affected / at risk	**0/21 (0.00%)**	**1/24 (4.17%)**
# events	**0**	**1**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 16.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 72 weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Vaniprevir 300 mg Bid + Peg-IFN + RBV	Participants received vaniprevir 300 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.
Vaniprevir 600 mg Bid + Peg-IFN + RBV	Participants received vaniprevir 600 mg twice daily in combination peg-IFN 180 mcg weekly and RBV 1000 or 1200 mg administered as a divided dose twice daily.

Other Adverse Events

	Vaniprevir 300 mg Bid + Peg-IFN + RBV	Vaniprevir 600 mg Bid + Peg-IFN + RBV
Total, other (not including serious) adverse events		
# participants affected / at risk	**21/21 (100.00%)**	**23/24 (95.83%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**5/21 (23.81%)**	**0/24 (0.00%)**
# events	**5**	**0**
Neutropenia † 1		
# participants affected / at risk	**2/21 (9.52%)**	**2/24 (8.33%)**
# events	**3**	**3**
Gastrointestinal disorders		
Abdominal distension † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**2**
Abdominal pain † 1		
# participants affected / at risk	**2/21 (9.52%)**	**3/24 (12.50%)**
# events	**2**	**3**
Abdominal pain upper † 1		
# participants affected / at risk	**2/21 (9.52%)**	**2/24 (8.33%)**
# events	**2**	**2**
Constipation † 1		
# participants affected / at risk	**2/21 (9.52%)**	**3/24 (12.50%)**

# events	3	3
Diarrhoea † 1		
# participants affected / at risk	5/21 (23.81%)	9/24 (37.50%)
# events	5	14
Dyspepsia † 1		
# participants affected / at risk	1/21 (4.76%)	2/24 (8.33%)
# events	1	2
Flatulence † 1		
# participants affected / at risk	0/21 (0.00%)	2/24 (8.33%)
# events	0	2
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	0/21 (0.00%)	3/24 (12.50%)
# events	0	3
Haemorrhoids † 1		
# participants affected / at risk	0/21 (0.00%)	3/24 (12.50%)
# events	0	3
Mouth ulceration † 1		
# participants affected / at risk	1/21 (4.76%)	3/24 (12.50%)
# events	1	3
Nausea † 1		
# participants affected / at risk	8/21 (38.10%)	14/24 (58.33%)
# events	8	17
Vomiting † 1		
# participants affected / at risk	3/21 (14.29%)	2/24 (8.33%)
# events	4	4
General disorders		
Asthenia † 1		
# participants affected / at risk	4/21 (19.05%)	6/24 (25.00%)
# events	4	6
Fatigue † 1		
# participants affected / at risk	7/21 (33.33%)	5/24 (20.83%)
# events	7	5
Influenza like illness † 1		
# participants affected / at risk	3/21 (14.29%)	4/24 (16.67%)
# events	4	4
Irritability † 1		
# participants affected / at risk	2/21 (9.52%)	3/24 (12.50%)
# events	2	3
Pyrexia † 1		
# participants affected / at risk	5/21 (23.81%)	3/24 (12.50%)
# events	6	3
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	2/21 (9.52%)	3/24 (12.50%)
# events	2	4

Urinary tract infection † 1		
# participants affected / at risk	**3/21 (14.29%)**	**0/24 (0.00%)**
# events	**4**	**0**
Injury, poisoning and procedural complications		
Accidental overdose † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**7**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**3**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**3**
Weight decreased † 1		
# participants affected / at risk	**2/21 (9.52%)**	**0/24 (0.00%)**
# events	**2**	**0**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**2/21 (9.52%)**	**5/24 (20.83%)**
# events	**3**	**5**
Hypokalaemia † 1		
# participants affected / at risk	**2/21 (9.52%)**	**0/24 (0.00%)**
# events	**2**	**0**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**4/21 (19.05%)**	**2/24 (8.33%)**
# events	**5**	**3**
Back pain † 1		
# participants affected / at risk	**1/21 (4.76%)**	**4/24 (16.67%)**
# events	**1**	**5**
Muscle spasms † 1		
# participants affected / at risk	**3/21 (14.29%)**	**1/24 (4.17%)**
# events	**3**	**1**
Myalgia † 1		
# participants affected / at risk	**3/21 (14.29%)**	**3/24 (12.50%)**
# events	**3**	**3**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**2/21 (9.52%)**	**3/24 (12.50%)**
# events	**4**	**4**
Headache † 1		
# participants affected / at risk	**7/21 (33.33%)**	**9/24 (37.50%)**
# events	**7**	**17**

Sciatica † 1		
# participants affected / at risk	**2/21 (9.52%)**	**0/24 (0.00%)**
# events	**2**	**0**
Tremor † 1		
# participants affected / at risk	**2/21 (9.52%)**	**0/24 (0.00%)**
# events	**2**	**0**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**3/21 (14.29%)**	**5/24 (20.83%)**
# events	**3**	**5**
Sleep disorder † 1		
# participants affected / at risk	**3/21 (14.29%)**	**5/24 (20.83%)**
# events	**4**	**5**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**2/21 (9.52%)**	**7/24 (29.17%)**
# events	**2**	**7**
Dyspnoea † 1		
# participants affected / at risk	**1/21 (4.76%)**	**2/24 (8.33%)**
# events	**1**	**2**
Oropharyngeal pain † 1		
# participants affected / at risk	**2/21 (9.52%)**	**3/24 (12.50%)**
# events	**2**	**3**
Productive cough † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**2**
Skin and subcutaneous tissue disorders		
Dermatitis † 1		
# participants affected / at risk	**1/21 (4.76%)**	**2/24 (8.33%)**
# events	**1**	**2**
Dry skin † 1		
# participants affected / at risk	**0/21 (0.00%)**	**2/24 (8.33%)**
# events	**0**	**2**
Eczema † 1		
# participants affected / at risk	**2/21 (9.52%)**	**3/24 (12.50%)**
# events	**2**	**3**
Erythema † 1		
# participants affected / at risk	**1/21 (4.76%)**	**3/24 (12.50%)**
# events	**1**	**3**
Pruritus † 1		
# participants affected / at risk	**5/21 (23.81%)**	**6/24 (25.00%)**
# events	**5**	**10**
Rash † 1		
# participants affected / at risk	**3/21 (14.29%)**	**1/24 (4.17%)**
# events	**3**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 16.0

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: ☐ 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. ☑ **Restriction Description:** The Sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

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No publications provided

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