Respiratory Syncytial Virus (RSV) Follow-Up Study (MK-0476-374)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01140048

First received: June 7, 2010
Last updated: July 18, 2016
Last verified: July 2016
History of Changes

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Purpose

This is a prospective, multicenter, observational study in participants who completed the 24-week, placebo-controlled MK-0476 Protocol 272 (NCT00076973) study of montelukast in the treatment of respiratory symptoms subsequent to RSV-induced bronchiolitis. The purpose of this study is to better understand the clinical and demographic correlates of asthma and atopic disorders in children (through the age of 6 years) with a history of severe RSV-induced bronchiolitis.

Condition
Respiratory Syncytial Virus Bronchiolitis

Study Type: Observational
Study Design: Observational Model: Cohort
Time Perspective: Prospective

Official Title: An Observational Follow-Up Study of Pediatric Patients Who Participated in a Previous Respiratory Syncytial Virus (RSV)-Induced Bronchiolitis Study of Montelukast

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

Primary Outcome Measures:

- Percentage of Participants With Asthma at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age] [Designated as safety issue: No]

  Asthma was defined as a positive response to the Epidemiology Questionnaire item "Has your child had wheezing or whistling in the chest in the past 6/12 months?" for the period of 12 months prior to age 6 years. Prognostic factors for asthma at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.

Secondary Outcome Measures:

- Percentage of Participants With Atopic Disorders at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age] [Designated as safety issue: No]

  Atopic disorders include allergic rhinitis (AR) and/or atopic dermatitis (AD). Atopic disorders was defined as a positive response to the Epidemiology Questionnaire item "In the past 6/12 months, has your child had a problem with sneezing or runny or blocked nose when he/she did not have a cold or the flu?" for AR and/or a positive response to both of the following items for AD: "Has your child had an itchy rash which was coming and going at any time in the past 6/12 months?" and "Has this itchy rash at any time affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears, or eyes?" for the period of 12 months prior to age 6 years. Prognostic factors for atopic disorders at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.

- Percentage of Participants With Use of Chronic Asthma Therapy at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age] [Designated as safety issue: No]

  Use of Chronic Asthma Therapy for the period of 12 months prior to the age of 6 years was defined by clinical review of reported concomitant medications. Prognostic factors for use of chronic asthma therapy at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.

Enrollment:	343
Study Start Date:	October 2007
Study Completion Date:	October 2011
Primary Completion Date:	October 2011 (Final data collection date for primary outcome measure)

Groups/Cohorts

All Enrolled Participants

All participants who completed Protocol 272 and were enrolled in Protocol 374

Eligibility

Ages Eligible for Study:	18 Months to 6 Years (Child)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

The study sample includes participants who completed all visits of Protocol 272 from approximately 38 study sites worldwide. Participants enrolled in Protocol 272 were 3- to 24-month-old children with their first or second episode of "severe" RSV-induced bronchiolitis.

Criteria

Inclusion Criteria:

- successfully completed MK-0476 Protocol 272
- had RSV-induced bronchiolitis at entry into Protocol 272

Exclusion Criteria:

- had developed or had been diagnosed with any illness or congenital disorder that could be immediately life threatening

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: NCT01140048

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Lu S, Hartert TV, Everard ML, Giezek H, Nelsen L, Mehta A, Patel H, Knorr B, Reiss TF. Predictors of asthma following severe respiratory syncytial virus (RSV) bronchiolitis in early childhood. Pediatr Pulmonol. 2016 May 6. doi: 10.1002/ppul.23461. [Epub ahead of print]

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01140048 History of Changes
Other Study ID Numbers:	**0476-374** 2010_026 MK-**0476-374**
Study First Received:	June 7, 2010
Results First Received:	August 31, 2012
Last Updated:	July 18, 2016
Health Authority:	United States: Institutional Review Board

Keywords provided by Merck Sharp & Dohme Corp.:
Asthma

Additional relevant MeSH terms:

Bronchiolitis	Lung Diseases, Obstructive
Bronchitis	Lung Diseases
Bronchial Diseases	Respiratory Tract Infections
Respiratory Tract Diseases	

ClinicalTrials.gov processed this record on October 12, 2016

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Results First Received: August 31, 2012

Study Type:	Observational
Study Design:	Observational Model: Cohort; Time Perspective: Prospective
Condition:	Respiratory Syncytial Virus Bronchiolitis

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
All Enrolled Participants	No text entered.

Participant Flow: Overall Study

	All Enrolled Participants
STARTED	343
COMPLETED	298
NOT COMPLETED	45
Physician Decision	1
Withdrawal by Subject	13
Lost to Follow-up	31

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
All Enrolled Participants	No text entered.

Baseline Measures

	All Enrolled Participants
Number of Participants [units: participants]	343
Age [units: months] Mean (Standard Deviation)	45.7 (10.0)
Gender [units: participants]	
Female	143
Male	200

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Asthma at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age]

Measure Type	Primary
Measure Title	Percentage of Participants With Asthma at 6 Years of Age: Overall and by Prognostic Factor

Measure Description	Asthma was defined as a positive response to the Epidemiology Questionnaire item "Has your child had wheezing or whistling in the chest in the past 6/12 months?" for the period of 12 months prior to age 6 years. Prognostic factors for asthma at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.
Time Frame	At 6 years of age
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.
All Enrolled Participants for whom data for the respective Epidemiology Questionnaire item at age 6 years and prognostic factors were available.

Reporting Groups

	Description
All Enrolled Participants	No text entered.

Measured Values

	All Enrolled Participants
Number of Participants Analyzed [units: participants]	**309**
Percentage of Participants With Asthma at 6 Years of Age: Overall and by Prognostic Factor [units: percentage of participants]	
With Asthma at Age 6 Years	**6.1**
Relative with Asthma: Yes	**11.2**
Relative with Asthma: No	**3.1**
Gender: Male	**9.6**
Gender: Female	**1.5**

No statistical analysis provided for Percentage of Participants With Asthma at 6 Years of Age: Overall and by Prognostic Factor

2. Secondary: Percentage of Participants With Atopic Disorders at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age]

Measure Type	Secondary
Measure Title	Percentage of Participants With Atopic Disorders at 6 Years of Age: Overall and by Prognostic Factor
Measure Description	Atopic disorders include allergic rhinitis (AR) and/or atopic dermatitis (AD). Atopic disorders was defined as a positive response to the Epidemiology Questionnaire item "In the past 6/12 months, has your child had a problem with sneezing or runny or blocked nose when he/she did not have a cold or the flu?" for AR and/or a positive response to both of the following items for AD: "Has your child had an itchy rash which was coming and going at any time in the past 6/12 months?" and "Has this itchy rash at any time affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears, or eyes?" for the period of 12 months prior to age 6 years.

	Prognostic factors for atopic disorders at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.
Time Frame	At 6 years of age
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.
All Enrolled Participants for whom data for the respective Epidemiology Questionnaire item at age 6 years and prognostic factors were available.

Reporting Groups

	Description
All Enrolled Participants	No text entered.

Measured Values

	All Enrolled Participants
Number of Participants Analyzed [units: participants]	**309**
Percentage of Participants With Atopic Disorders at 6 Years of Age: Overall and by Prognostic Factor [units: percentage of participants]	
With Atopic Disorders at Age 6 Years	**36.2**
History of AR: Yes	**65.1**
History of AR: No	**25.0**
Relative with Asthma: Yes	**47.4**
Relative with Asthma: No	**29.2**

No statistical analysis provided for Percentage of Participants With Atopic Disorders at 6 Years of Age: Overall and by Prognostic Factor

3. Secondary: Percentage of Participants With Use of Chronic Asthma Therapy at 6 Years of Age: Overall and by Prognostic Factor [Time Frame: At 6 years of age]

Measure Type	Secondary
Measure Title	Percentage of Participants With Use of Chronic Asthma Therapy at 6 Years of Age: Overall and by Prognostic Factor
Measure Description	Use of Chronic Asthma Therapy for the period of 12 months prior to the age of 6 years was defined by clinical review of reported concomitant medications. Prognostic factors for use of chronic asthma therapy at age 6 years were derived from baseline characteristic, disease characteristic and family history data, and were identified by a forward stepwise regression model.
Time Frame	At 6 years of age
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.
All Enrolled Participants for whom data on concomitant asthma therapy at age 6 years and prognostic factors were available.

Reporting Groups

	Description
All Enrolled Participants	No text entered.

Measured Values

	All Enrolled Participants
Number of Participants Analyzed [units: participants]	**310**
Percentage of Participants With Use of Chronic Asthma Therapy at 6 Years of Age: Overall and by Prognostic Factor [units: percentage of participants]	
With Use of Chronic Asthma Therapy at Age 6 Years	**14.5**
History of Asthma: Yes	**32.0**
History of Asthma: No	**6.6**
Region: Africa	**22.5**
Region: Europe	**20.3**
Region: South America	**15.9**
Region: Asia/Pacific	**7.3**
Region: North & Central America	**5.7**

No statistical analysis provided for Percentage of Participants With Use of Chronic Asthma Therapy at 6 Years of Age: Overall and by Prognostic Factor

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Serious adverse events that occurred within 24 hours following a study procedure
Additional Description	Only serious adverse events related to study-defined procedures that occurred within 24 hours following the procedure were to be reported. Information on non-serious adverse events was not to be collected.

Reporting Groups

	Description
All Enrolled Participants	No text entered.

Serious Adverse Events

	All Enrolled Participants

Total, serious adverse events	
# participants affected / at risk	**0/343 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Serious adverse events that occurred within 24 hours following a study procedure
Additional Description	Only serious adverse events related to study-defined procedures that occurred within 24 hours following the procedure were to be reported. Information on non-serious adverse events was not to be collected.

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
All Enrolled Participants	No text entered.

Other Adverse Events

	All Enrolled Participants
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/0**

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:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Lu S, Hartert TV, Everard ML, Giezek H, Nelsen L, Mehta A, Patel H, Knorr B, Reiss TF. Predictors of asthma following severe respiratory syncytial virus (RSV) bronchiolitis in early childhood. Pediatr Pulmonol. 2016 May 6. doi: 10.1002/ppul.23461. [Epub ahead of print]

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