Safety and Efficacy of Quadriderme® in the Treatment of Impetiginous Eczema (Study P05134AM4)

This study has been terminated.

(terminated early due to lack of recruitment [only 3 of 207 subjects were enrolled])

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00671528

First received: May 1, 2008
Last updated: December 29, 2014
Last verified: December 2014
History of Changes

Purpose

This is a parallel-group, randomized, active-controlled, double-blind, Phase 4 trial comparing three creams in the treatment of impetiginous eczema:

- Arm A: QUADRIDERME® cream (betamethasone diproprionate, clotrimazole, and gentamicin sulfate)
- Arm B: Combination of betamethasone diproprionate cream and gentamicin sulfate cream
- Arm C: Betamethasone diproprionate cream

At 7 sites, in Portugal, a total of 207 subjects will be randomized using a 1:1:1 randomization ratio to receive one of the three possible treatments for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days. Assessments will be made of level of improvement of the target area in each treatment group, number of days for total remission, and safety profile.

Note: This study was terminated early due to lack of recruitment (only 3 of the 207 planned participants were enrolled). Statistical analyses were not performed.

Further, 7 sites were planned, but only 4 sites were approved out of which 3 sites were initiated.

Condition	Intervention	Phase
Dermatitis, Atopic Eczema, Atopic Skin Diseases, Eczematous	Drug: Cream (betamethasone diproprionate, clotrimazole, and gentamicin sulfate) Drug: Cream (betamethasone diproprionate and gentamicin) Drug: Cream (betamethasone diproprionate)	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Double-blind Evaluation of the Safety and Efficacy of Quadriderme® (Betamethasone Diproprionate, Clotrimazole and Gentamicin) Compared With Betamethasone Diproprionate Combined With Gentamicin Sulfate and With Betamethasone Diproprionate in the

Treatment of Impetiginous Eczema

Resource links provided by NLM:

Genetics Home Reference related topics: atopic dermatitis

MedlinePlus related topics: Eczema Skin Conditions

Drug Information available for: Betamethasone sodium phosphate Betamethasone Gentamicin Gentamicin sulfate Betamethasone valerate Betamethasone dipropionate Sulfate ion Clotrimazole

U.S. FDA Resources

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

Primary Outcome Measures:

- Percent Improvement of Individually Measured Signs of the Disease [Time Frame: Days 1 (prior to start of treatment), 8, 15, 21, and 28.] [Designated as safety issue: No]

  Percent improvement of individually measured signs of the disease (erythema, vesiculation, scaling, pruritis) in a given target area that was chosen by the investigator was assessed objectively & quantified on a scale of 0-5 (0-absent, 5-very intense). Overall assessment reflected the changes in the disease & was carried out by the investigator. The following scale was used:

  a. Cure- Complete remission
  b. > 75% reduction: Marked improvement
  c. 50-75% reduction: Moderate improvement
  d. 25-50% reduction: Slight improvement
  e. <25% reduction: Ineffectiveness
  f. Worsening of signs & symptoms

Secondary Outcome Measures:

- Number of Days Required to Achieve Total Remission [Time Frame: Up to 28 days] [Designated as safety issue: No]

  The speed of action, measured as the number of days required to achieve total remission of all signs and symptoms of the disease.

Enrollment:	3
Study Start Date:	July 2009
Study Completion Date:	May 2010
Primary Completion Date:	May 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: QUADRIDERME® cream QUADRIDERME® cream (betamethasone diproprionate, clotrimazole, and gentamicin sulfate)	Drug: Cream (betamethasone diproprionate, clotrimazole, and gentamicin sulfate) Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% cream applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days. Other Name: QUADRIDERME® cream, SCH 000411
Active Comparator: Betamethasone and Gentamicin Combination of betamethasone diproprionate cream and gentamicin sulfate cream	Drug: Cream (betamethasone diproprionate and gentamicin) Betamethasone diproprionate 0.05% and gentamicin sulfate 0.1% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Active Comparator: Betamethasone Betamethasone diproprionate	Drug: Cream (betamethasone diproprionate) Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs

cream	and symptoms, but never more than 28 days.

Eligibility

Ages Eligible for Study: 12 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Minimum age: 12 years
- Good general health confirmed by clinical history and a physical and skin examination (excluding area of skin with impetiginous eczema).
- Diagnosis of impetiginous eczema.
- Ability to understand the procedures of the protocol and follow the requirements during the course of the study.
- Results of routine laboratory tests - hemogram with leukogram and platelet count, creatinine, glucose, sed. rate, IgE level and transaminases; along with plasma cortisol and adrenocorticotropic hormone (ACTH) levels prior to the start of the treatment. These results must all be within normal limits or not clinically relevant in order to be included in the trial.

Exclusion Criteria:

- Pregnant participants or women of childbearing age who are not using birth control methods considered reliable by the attending physician.
- Participants with a history of hypersensitivity to any of the components of the medication being studied.
- Participants in whom the extent or severity of the lesions requires treatment of a different type than what is planned for this trial.
- Participants who need any other type of topical or systemic medication during the trial that might affect the course of the disease.
- Participants who have been treated with other topical medications during the 14-day period prior to the start of the trial.
- Participants who have received systemic corticosteroids or any other immunosuppressant medication during the 28-day period prior to the start of the 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.

No Contacts or Locations Provided

More Information

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00671528 History of Changes
Other Study ID Numbers: P05134 EudraCT No.: 2007-004980-23
Study First Received: May 1, 2008
Results First Received: May 19, 2011
Last Updated: December 29, 2014
Health Authority: Portugal: National Pharmacy and Medicines Institute

Keywords provided by Merck Sharp & Dohme Corp.:
Impetiginous

Additional relevant MeSH terms:

Dermatitis	Gentamicins
Dermatitis, Atopic	Anti-Asthmatic Agents
Eczema	Anti-Bacterial Agents
Skin Diseases	Anti-Infective Agents
Skin Diseases, Eczematous	Anti-Inflammatory Agents
Genetic Diseases, Inborn	Enzyme Inhibitors
Hypersensitivity	Glucocorticoids

Hypersensitivity, Immediate
Immune System Diseases
Skin Diseases, Genetic
Betamethasone
Betamethasone Valerate
Betamethasone benzoate
Betamethasone sodium phosphate
Betamethasone-17,21-dipropionate

Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Protein Synthesis Inhibitors
Respiratory System Agents
Therapeutic Uses

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History of Changes

Results First Received: May 19, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Dermatitis, Atopic Eczema, Atopic Skin Diseases, Eczematous
Interventions:	Drug: Cream (betamethasone diproprionate, clotrimazole, and gentamicin sulfate) Drug: Cream (betamethasone diproprionate and gentamicin) Drug: Cream (betamethasone diproprionate)

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

Due to lack of recruitment, the study was terminated early. Only 3 participants of the anticipated 207 participants were enrolled.

Reporting Groups

	Description
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate and Gentamicin Sulfate Cream	Combination of Betamethasone diproprionate 0.05% cream and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Participant Flow: Overall Study

	Quadriderme® Cream	Betamethasone Diproprionate and Gentamicin Sulfate Cream	Betamethasone Diproprionate Cream
STARTED	**1**	**1**	**1**
COMPLETED	**1**	**1**	**1**
NOT COMPLETED	**0**	**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
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate and Gentamicin Sulfate Cream	Combination of Betamethasone diproprionate 0.05% cream and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Total	Total of all reporting groups

Baseline Measures

	Quadriderme® Cream	Betamethasone Diproprionate and Gentamicin Sulfate Cream	Betamethasone Diproprionate Cream	Total
Number of Participants [units: participants]	**1**	**1**	**1**	**3**
Age, Customized [units: participants]				
Between 18 and 65 years	**0**	**0**	**1**	**1**
>=65 years	**1**	**1**	**0**	**2**
Gender [units: participants]				
Female	**1**	**0**	**1**	**2**
Male	**0**	**1**	**0**	**1**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Improvement of Individually Measured Signs of the Disease [Time Frame: Days 1 (prior to start of treatment), 8, 15, 21, and 28.]

Measure Type	Primary
Measure Title	Percent Improvement of Individually Measured Signs of the Disease
Measure Description	Percent improvement of individually measured signs of the disease (erythema, vesiculation, scaling, pruritis) in a given target area that was chosen by the investigator was assessed objectively & quantified on a scale of 0-5 (0-absent, 5-very intense). Overall assessment reflected the changes in the disease & was carried out by the investigator. The following scale was used: 1. Cure- Complete remission 2. > 75% reduction: Marked improvement 3. 50-75% reduction: Moderate improvement 4. 25-50% reduction: Slight improvement 5. <25% reduction: Ineffectiveness 6. Worsening of signs & symptoms
Time Frame	Days 1 (prior to start of treatment), 8, 15, 21, and 28.
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.
Due to lack of participant recruitment and therefore study termination, no analyses were performed.

Reporting Groups

	Description
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate and Gentamicin Sulfate Cream	Combination of Betamethasone diproprionate 0.05% cream and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Measured Values

	Quadriderme® Cream	Betamethasone Diproprionate and Gentamicin Sulfate Cream	Betamethasone Diproprionate Cream
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**
Percent Improvement of Individually Measured Signs of the Disease			

No statistical analysis provided for Percent Improvement of Individually Measured Signs of the Disease

2. Secondary: Number of Days Required to Achieve Total Remission [Time Frame: Up to 28 days]

Measure Type	Secondary
Measure Title	Number of Days Required to Achieve Total Remission
Measure Description	The speed of action, measured as the number of days required to achieve total remission of all signs and symptoms of the disease.
Time Frame	Up to 28 days
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.
No text entered.

Reporting Groups

	Description
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate and Gentamicin Sulfate Cream	Combination of Betamethasone diproprionate 0.05% cream and gentamicin

	sulfate 0.1% applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Measured Values

	Quadriderme® Cream	Betamethasone Diproprionate and Gentamicin Sulfate Cream	Betamethasone Diproprionate Cream
Number of Participants Analyzed [units: participants]	**1**	**1**	**1**
Number of Days Required to Achieve Total Remission [units: Days]	**15**	**15**	**8**

No statistical analysis provided for Number of Days Required to Achieve Total Remission

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate and Gentamicin Sulfate Cream	Combination of Betamethasone diproprionate 0.05% cream and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Serious Adverse Events

	Quadriderme® Cream	Betamethasone Diproprionate and Gentamicin Sulfate Cream	Betamethasone Diproprionate Cream
Total, serious adverse events			

# participants affected / at risk	**0/1 (0.00%)**	**0/1 (0.00%)**	**0/1 (0.00%)**

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
Quadriderme® Cream	Combination of Betamethasone diproprionate 0.05%, clotrimazole 1%, and gentamicin sulfate 0.1% applied in a thin layer that covers the affected and surrounding area 2 times a day (BID), morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.
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Betamethasone Diproprionate Cream	Betamethasone diproprionate 0.05% cream applied in a thin layer that covers the affected and surrounding area BID, morning and night for a maximum period of 28 days or until 5 days after total remission of the signs and symptoms, but never more than 28 days.

Other Adverse Events

	Quadriderme® Cream	**Betamethasone Diproprionate and Gentamicin Sulfate Cream**	**Betamethasone Diproprionate Cream**
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/1 (0.00%)**	**0/1 (0.00%)**	**0/1 (0.00%)**

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
This study was terminated early due to lack of recruitment (only 3 of 201 participants were enrolled). Statistical analyses were not performed.

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 principal investigators agree not to publish or publicly present any interim results of the study without prior written consent of the SPONSOR. The principal investigator further agrees to provide 45 days written notice to the sponsor prior to submission for publication or presentation to permit the SPONSOR to review copies of abstracts or manuscripts for publication which report any results of the study. The SPONSOR shall have the right to review and comment on any presentation.

Results Point of Contact:

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

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Health Authority:	Portugal: National Pharmacy and Medicines Institute

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