



Clinical trial results:

Epicutaneous Immunotherapy (EPIT) for Peanut Allergy: A Randomized, Double-Blind, Placebo-Controlled Phase I Safety Study in Adult and Pediatric Subjects

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2018-000868-29 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 27 February 2012 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 04 October 2022 |
| First version publication date | 04 October 2022 |
| Summary attachment (see zip file) | V712-101 CSR Synopsis (V712-101-synopsis_Redacted.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | V712-101 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01170286 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | DBV Technologies |
| Sponsor organisation address | 177/181 Avenue Pierre Brossolette, Montrouge, France, 92120 |
| Public contact | Chief Medical Officer, DBV Technologies, +33 1 55 42 78 78, clinicaltrials@dbv-technologies.com |
| Scientific contact | Chief Medical Officer, DBV Technologies, +33 1 55 42 78 78, clinicaltrials@dbv-technologies.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001481-PIP01-13 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 February 2012 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 February 2012 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of repeated application of Viaskin™ patch (DBV712) in adult, adolescent, and child subjects with a known allergy to peanuts.

Protection of trial subjects:

The Investigators obtained consent from each participant in the study, in accordance with the International Council for Harmonization-Good Clinical Practice Guidelines, the Declaration of Helsinki, and applicable regulatory requirements, prior to entering the study. Participants were informed of the nature of the study, its aim, its possible risks and restrictions, its duration, and the compensation that they were to receive. Participants were required to read, sign, and date the Institutional Review Board (IRB)-approved consent form. Children aged 6 to 11 years were required to sign a separate child assent form. Adolescents 12 to 17 years of age were also given the option of signing the Informed Consent Form (ICF) child assent line. The parents or legal representative(s) of all minors, regardless of age, were also required to sign the ICF.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 21 July 2010 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 100 |
| Worldwide total number of subjects | 100 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 10 |
| Adolescents (12-17 years) | 20 |

| | |
|----------------------|----|
| Adults (18-64 years) | 70 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

This Phase 1, placebo-controlled, dose-escalation safety study was conducted in adults, adolescents and children at 5 centers in the United States. The study included severe (anaphylaxis reactions of grade 4 or 5) and nonsevere (anaphylaxis reactions grade ≤ 3) peanut allergic adults and only nonsevere peanut adolescents and children.

Pre-assignment

Screening details:

The study included 3 periods; Screening period (up to 90 days), Treatment period (15 days) and Follow-up period (7 days after last dose). A total of 100 participants were enrolled in this study.

Period 1

| | |
|------------------------------|---------------------------------------|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Carer |

Arms

| | |
|------------------------------|-----------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Viaskin™ Peanut: All Participants |

Arm description:

Participants applied Viaskin™ Peanut patches (20 microgram [mcg], 100 mcg, 250 mcg, and 500 mcg) on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. The recommended starting dose of Viaskin™ Peanut was 20 mcg and dose escalated up to 500 mcg.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Viaskin™ Peanut |
| Investigational medicinal product code | DBV712 |
| Other name | |
| Pharmaceutical forms | Cutaneous patch |
| Routes of administration | Epicutaneous use |

Dosage and administration details:

Viaskin™ Peanut epicutaneous patch containing a solid deposit of formulated peanut protein extract applied on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. The drug substance is an unmodified, lyophilized peanut extract produced from the extraction and freeze drying of defatted peanut flour.

| | |
|------------------|---------------------------|
| Arm title | Placebo: All Participants |
|------------------|---------------------------|

Arm description:

Participants applied placebo patches on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks.

| | |
|--|------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous patch |
| Routes of administration | Epicutaneous use |

Dosage and administration details:

Placebo epicutaneous patch applied on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks.

| Number of subjects in period 1 | Viaskin™ Peanut: All Participants | Placebo: All Participants |
|---------------------------------------|-----------------------------------|---------------------------|
| Started | 80 | 20 |
| Completed | 77 | 19 |
| Not completed | 3 | 1 |
| Protocol noncompliance | - | 1 |
| Consent withdrawn by subject | 1 | - |
| Adverse event, non-fatal | 2 | - |

Baseline characteristics

Reporting groups

| | |
|--|-----------------------------------|
| Reporting group title | Viaskin™ Peanut: All Participants |
| Reporting group description: | |
| Participants applied Viaskin™ Peanut patches (20 microgram [mcg], 100 mcg, 250 mcg, and 500 mcg) on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. The recommended starting dose of Viaskin™ Peanut was 20 mcg and dose escalated up to 500 mcg. | |
| Reporting group title | Placebo: All Participants |
| Reporting group description: | |
| Participants applied placebo patches on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. | |

| Reporting group values | Viaskin™ Peanut: All Participants | Placebo: All Participants | Total |
|--|-----------------------------------|---------------------------|-------|
| Number of subjects | 80 | 20 | 100 |
| Age categorical Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 24.7 | 22.2 | |
| standard deviation | ± 11.56 | ± 9.18 | - |
| Gender categorical Units: Subjects | | | |
| Female | 30 | 10 | 40 |
| Male | 50 | 10 | 60 |
| Race Units: Subjects | | | |
| White | 62 | 16 | 78 |
| Black | 16 | 3 | 19 |
| Asian | 1 | 0 | 1 |
| Other | 1 | 1 | 2 |
| Ethnicity Units: Subjects | | | |
| Hispanic | 4 | 2 | 6 |
| Non-Hispanic | 76 | 18 | 94 |

End points

End points reporting groups

| | |
|--|-----------------------------------|
| Reporting group title | Viaskin™ Peanut: All Participants |
| Reporting group description: Participants applied Viaskin™ Peanut patches (20 microgram [mcg], 100 mcg, 250 mcg, and 500 mcg) on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. The recommended starting dose of Viaskin™ Peanut was 20 mcg and dose escalated up to 500 mcg. | |
| Reporting group title | Placebo: All Participants |
| Reporting group description: Participants applied placebo patches on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. | |

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious TEAEs

| | |
|--|--|
| End point title | Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious TEAEs ^[1] |
| End point description: The TEAEs were defined as adverse events (AEs), regardless of relationship to study drug, which occurred during or after initial Viaskin™ patch application, or any event already present before randomization that worsened in either intensity or frequency following exposure to Viaskin™ patch. A serious AE was defined as any untoward medical occurrence at any dose that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or was an important medical event. | |
| End point type | Primary |
| End point timeframe: From Day 1 up to end of study, approximately 22 days | |
| Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Only descriptive statistical analysis was performed for the primary endpoint. | |

| End point values | Viaskin™ Peanut: All Participants | Placebo: All Participants | | |
|-----------------------------|-----------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 20 | | |
| Units: participants | | | | |
| TEAEs | 75 | 15 | | |
| Serious TEAEs | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Treated for Systemic Reactions of Special Interest Related to DBV712 Treatment

| | |
|-----------------|---|
| End point title | Percentage of Participants Treated for Systemic Reactions of Special Interest Related to DBV712 Treatment |
|-----------------|---|

End point description:

Any occurrence of anaphylaxis or systemic allergic reactions directly related to DBV712 application was considered an AE of special interest. The safety analysis set included all randomized participants who received any amount of study drug.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Day 1 up to end of study, approximately 22 days

| End point values | Viaskin™ Peanut: All Participants | Placebo: All Participants | | |
|-----------------------------------|---|------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 20 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 11.3 | 5.0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Compliance to the Study Treatment

| | |
|-----------------|---|
| End point title | Overall Compliance to the Study Treatment |
|-----------------|---|

End point description:

Overall adherence to the study treatment, as measured by compliance, was assessed by study drug accountability information, which was recorded on the Viaskin™ accountability case report form. For participants under the 24-hour regimen, it was calculated as $100 \times (\text{total number of Viaskin™ patches used}) / (\text{duration of exposure} - 1)$ and for participants under the 48-hour regimen, it was calculated as $100 \times 2 \times (\text{total number of Viaskin™ patches used}) / (\text{duration of exposure} - 1)$. The safety analysis set included all randomized participants who received any amount of study drug.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Day 1 to Day 15

| End point values | Viaskin™ Peanut: All Participants | Placebo: All Participants | | |
|---|---|------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 79 | 20 | | |
| Units: percentage of epicutaneous patches | | | | |
| arithmetic mean (standard deviation) | 100.18 (± 4.568) | 101.07 (± 3.494) | | |

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

TEAEs were collected from Day 1 up to end of study, approximately 22 days.

Adverse event reporting additional description:

The safety analysis set included all randomized participants who received any amount of study drug.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 13.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Viaskin™ Peanut: All Participants |
|-----------------------|-----------------------------------|

Reporting group description:

Participants applied Viaskin™ Peanut patches (20 mcg, 100 mcg, 250 mcg, and 500 mcg) on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks. The recommended starting dose of Viaskin™ Peanut was 20 mcg and dose escalated up to 500 mcg.

| | |
|-----------------------|---------------------------|
| Reporting group title | Placebo: All Participants |
|-----------------------|---------------------------|

Reporting group description:

Participants applied placebo patches on intact skin either daily for 24 hours or every other day for 48 hours for 2 weeks.

| Serious adverse events | Viaskin™ Peanut: All Participants | Placebo: All Participants | |
|---|-----------------------------------|---------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 80 (0.00%) | 0 / 20 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Viaskin™ Peanut: All Participants | Placebo: All Participants | |
|---|-----------------------------------|---------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 75 / 80 (93.75%) | 15 / 20 (75.00%) | |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Contusion | | | |

| | | | |
|--|-------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 80 (0.00%) 0 | 1 / 20 (5.00%) 1 | |
| Heat exhaustion subjects affected / exposed occurrences (all) | 0 / 80 (0.00%) 0 | 1 / 20 (5.00%) 1 | |
| Joint sprain subjects affected / exposed occurrences (all) | 0 / 80 (0.00%) 0 | 1 / 20 (5.00%) 1 | |
| Vascular disorders Pallor subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 7 / 80 (8.75%) 12 | 6 / 20 (30.00%) 6 | |
| Migraine subjects affected / exposed occurrences (all) | 2 / 80 (2.50%) 2 | 0 / 20 (0.00%) 0 | |
| Paraesthesia mucosal subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| General disorders and administration site conditions Application site pruritus subjects affected / exposed occurrences (all) | 66 / 80 (82.50%) 641 | 10 / 20 (50.00%) 68 | |
| Application site erythema subjects affected / exposed occurrences (all) | 56 / 80 (70.00%) 508 | 5 / 20 (25.00%) 13 | |
| Application site urticaria subjects affected / exposed occurrences (all) | 40 / 80 (50.00%) 273 | 3 / 20 (15.00%) 7 | |
| Application site oedema subjects affected / exposed occurrences (all) | 38 / 80 (47.50%) 194 | 1 / 20 (5.00%) 1 | |
| Application site anaesthesia | | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Application site pain | | | |
| subjects affected / exposed | 0 / 80 (0.00%) | 1 / 20 (5.00%) | |
| occurrences (all) | 0 | 1 | |
| Immune system disorders | | | |
| Allergy to animal | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 1 / 20 (5.00%) | |
| occurrences (all) | 2 | 3 | |
| Food allergy | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Eye oedema | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Eye pruritus | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eyelid oedema | | | |

| | | | |
|---|---------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Lacrimation increased subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Orbital oedema subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 2 / 80 (2.50%) 2 | 0 / 20 (0.00%) 0 | |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 80 (2.50%) 2 | 0 / 20 (0.00%) 0 | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 2 / 20 (10.00%) 3 | |
| Lip oedema subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Mouth ulceration subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Nausea subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal congestion subjects affected / exposed occurrences (all) | 4 / 80 (5.00%) 5 | 0 / 20 (0.00%) 0 | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 3 / 80 (3.75%) 3 | 0 / 20 (0.00%) 0 | |
| Rhinorrhoea | | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 3 / 80 (3.75%) | 0 / 20 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Cough | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinalgia | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sneezing | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Throat irritation | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Wheezing | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Rash | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 0 / 20 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Urticaria | | | |
| subjects affected / exposed | 2 / 80 (2.50%) | 1 / 20 (5.00%) | |
| occurrences (all) | 2 | 1 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|--|---------------------|---------------------|--|
| Eczema subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 80 (0.00%) 0 | 1 / 20 (5.00%) 1 | |
| Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Musculoskeletal stiffness subjects affected / exposed occurrences (all) | 2 / 80 (2.50%) 2 | 0 / 20 (0.00%) 0 | |
| Back pain subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Pain in extremity subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Neck pain subjects affected / exposed occurrences (all) | 0 / 80 (0.00%) 0 | 1 / 20 (5.00%) 2 | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 4 / 80 (5.00%) 4 | 0 / 20 (0.00%) 0 | |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 2 / 80 (2.50%) 2 | 0 / 20 (0.00%) 0 | |
| Gastroenteritis viral subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |
| Pharyngitis streptococcal subjects affected / exposed occurrences (all) | 1 / 80 (1.25%) 1 | 0 / 20 (0.00%) 0 | |

| | | | |
|---|----------------|----------------|--|
| Sinusitis | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 80 (1.25%) | 0 / 20 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arthritis infective | | | |
| subjects affected / exposed | 0 / 80 (0.00%) | 1 / 20 (5.00%) | |
| occurrences (all) | 0 | 1 | |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 80 (0.00%) | 1 / 20 (5.00%) | |
| occurrences (all) | 0 | 1 | |
| Skin infection | | | |
| subjects affected / exposed | 0 / 80 (0.00%) | 1 / 20 (5.00%) | |
| occurrences (all) | 0 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 24 June 2010 | Amended to clarify the study design in response to questions from the Central IRB for severe adult participants and Food and Drug Administration. |
| 15 September 2010 | Amended to change the inclusion criteria of the peanut-specific immunoglobulin E threshold value in inclusion criterion from ≥ 5 kilounits per liter (kU/L) to >0.7 kU/L. |
| 09 February 2011 | Amended to clarify the conditions or circumstances in which the Viaskin™ patches must be removed earlier than the recommended durations of application (24 hours or 48 hours) in order to reinforce participant safety. Immediate removal of the Viaskin™ patch must occur in the case of an important local AE or in the case of any distant or systemic AE. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported