

# Safety Study of Viaskin® Peanut Patch in Peanut-Allergic Children 1 Through 3 Years of Age (COMFORT Toddlers)

NCT07003919

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Status	RECRUITING
Phase	Phase 3
Sponsor	DBV Technologies
Enrollment	480 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Aged 1 through 3 years at Visit 1 (screening).
- Physician-diagnosed peanut allergy and following a strict peanut-free diet
- Peanut-specific IgE  $\geq$  0.7 kUA/L.
- A positive peanut SPT with the largest wheal diameter of  $\geq$  6 mm at Visit 1 (screening).
- An ED of 300 mg peanut protein at screening double-blind placebo-controlled food challenge (DBPCFC).

### Exclusion (6)

- Peanut allergic subjects presenting a medical history of severe anaphylaxis to peanut.
- Severe generalized dermatologic disease involving the proposed treatment application area (interscapular region).
- Current immunotherapy for any allergen (including food allergy, allergic rhinitis and/or insect allergy).
- History of any immunotherapy for peanut allergy, including Epicutaneous immunotherapy (EPIT), oral immunotherapy (OIT), sublingual immunotherapy (SLIT).
- Treatment with any monoclonal antibody or biologic immunomodulatory therapy within 6 months prior to Visit 1.

... and 1 more (see full listing online)

## Locations (90 total)

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AllerVie Clinical Research, Birmingham, Alabama, United States  
University of Alabama at Birmingham Pediatric Primary Care Clinic, Birmingham, Alabama, United States  
Modena Allergy & Asthma, Scottsdale, Arizona, United States  
... and 87 more locations