IMMUNOTHERAPY WITH PEANUT PATCH IN TODDLERS

DBPCFCs were conducted per the PRACTALL guidelines (VP250 using a...)

This poster describes a prespecified outcome, change in severity of...

Bradycardia vs 33.5% in the placebo group.

Tachycardia – R, 2

Timothée

28.6%

There is currently no approved treatment for peanut allergy in...

Moreover, 2

Juan Trujillo, A, Cooper SF, Krombholz K, Culliney C, Culliney A, Matlock T...

Peanut allergy often develops in infancy. Accidental exposures may...

A, Matlock T.

Dose

12

Nearly twice as many participants in the VP250 group (36.5%)

• Baseline demographic characteristics for the VP250...

284 randomized to VP250 and 98/118 randomized to placebo completed both the baseline and Month 12 DBPCFCs and were included in this analysis.

• Baseline demographic characteristics for the VP250 and placebo groups were balanced.

At baseline DBPCFC, the proportions of reaction severity (based on...

Peanut allergy often develops in infancy. Accidental exposures may...

VP250 among children aged 1 to <4 years (VP250 vs 1...)

EPITOPE was a multicenter, randomized, double...

Two major goals of food allergy immunotherapy are to induce...

The median change in ED from baseline to Month 12 was...

A, Cooper SF, Krombholz K, Culliney C, Culliney A, Matlock T...

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Figure 1: Study Design Diagram

Figure 2: Maximum Symptom Severity During DBPCFC

Figure 3: Maximum Symptom Severity by Month 12 ED

Table 1: Signs/Symptoms Collected During DBPCFC to Determine Stopping Criteria – All Assessable Organ Systems

Table: Signs/Symptoms Collected During DBPCFC to Determine Stopping Criteria – All Assessable Organ Systems

Skin

• Pruritus

• Elicitation of rash or mild rash over affected area

• Thermometer

• Upper Respiratory

• Nasal congestion

• Irritation

• Lower Respiratory

• Wheezing

• Gastrointestinal

• Diarrhea

• Vomiting

• Pain

• Cardiovascular

• Tachycardia

• Bradycardia

• Hypertension

• Hypotension

• Hypothermia

• Hyperthermia

• Eyes

• Conjunctivitis

RESULTS

Among all participants, 200/244 randomized to VP250 and 98/118 randomized to placebo completed both the baseline and Month 12 DBPCFCs and were included in this analysis.

Baseline DBPCFC: VP250 among toddlers aged 1 to <4 years, demonstrating a strong unmet need for an available treatment.

There is currently no approved treatment for peanut allergy in children aged 4 years, demonstrating a strong unmet need for an available treatment.

Visilin, a patch-based technology platform, is currently being investigated for the treatment of peanut allergy. This novel approach to epicutaneous immunotherapy (EPT) involves the administration of a patch (VP250) containing 250 µg (~1/100 of 1 peanut) of peanut antigen to intact skin in order to induce desensitization.

The phase 3 trial in Toddlers with Peanut Allergy (EPTOPE) (NCT03321241) aimed to assess the efficacy and safety of EPT with VP250 among children aged 1 to 4 years with peanut allergy.

The study demonstrated that 12 months of daily EPT with VP250 was statistically superior to placebo in desensitizing peanut-allergic children aged 1 to 4 years, with 67% in the VP250 group being treatment responders versus 33.3% in the placebo group (difference: 33.4%; 95% CI: 22.4, 44.5 [P<0.001]).

Eliciting score of "absent" or "mild", as compared to the participants in the placebo group [19.4%]

The shift toward reaction severity reduction coincided with an increase in ED and a greater proportion of responders in the VP250 group vs placebo (Figure 3)

The median change in ED was 190 mg for the VP250 group vs 0 mg in the placebo group

This analysis suggests that, in addition to achieving desensitization in peanut-allergic children 1 to 4 years, EPT with a patch containing 250 µg peanut protein may also reduce the severity of accidental ingestion reactions.

The study results suggest that VP250 treatment has the potential to help address dual goals of immunotherapy: decreasing the likelihood of reactions to accidental ingestion of allergens and reducing reaction severity.

METHODS

EPTOPE was a multicenter, randomized, double-blind, placebo-controlled phase 3 trial that evaluated the efficacy and safety of EPT with VP250 among toddlers aged 1 to 4.5 years (Figure 1)

• 342 participants were randomized 2:1 to receive either the VP250 patch or the placebo patch daily for 12 months

CONCLUSIONS

This study additionally suggests that, in addition to achieving desensitization in peanut-allergic children 1 to 4 years, EPT with a patch containing 250 µg peanut protein may also reduce the severity of accidental ingestion reactions.

Moreover, the results of this study showed a shift toward a reduction in reaction severity that coincided with an increase in ED and a greater proportion of responders in the VP250 group vs placebo.

The study results suggest that VP250 treatment has the potential to help address dual goals of immunotherapy: decreasing the likelihood of reactions to accidental ingestion of allergens and reducing reaction severity.

RATIONALER

• Peanut allergy often develops in infancy. Accidental exposures may occur, often resulting in severe reactions, including anaphylaxis.

• Studies have shown that early oral introduction of peanuts in children could reduce the risk of developing peanut allergy, suggesting that the immune system in young children may be particularly sensitive to immunomodulation.

• Two major goals of food allergy immunotherapy are to induce desensitization (i.e., increase the reaction threshold), thereby reducing reaction risk from accidental ingestion, and reduce reaction severity.

• There is currently no approved treatment for peanut allergy in children aged 4 years, demonstrating a strong unmet need for an available treatment.

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• Studies have shown that early oral introduction of peanuts in children could reduce the risk of developing peanut allergy, suggesting that the immune system in young children may be particularly sensitive to immunomodulation.

• Two major goals of food allergy immunotherapy are to induce desensitization (i.e., increase the reaction threshold), thereby reducing reaction risk from accidental ingestion, and reduce reaction severity.