

Food Allergy and Oral Immunotherapy

Neeraj Dutta*

Centre for Advanced Studies, Dr. A.P.J. Abdul Kalam Technical University, Lucknow, India

ABOUT THE STUDY

What is food allergy?

When the immune system of the body reacts abnormally to food, it is called a food allergy.

Food allergies have no recognized cause. Allergies that began in childhood may disappear in maturity in certain situations. Symptoms of an allergic response include stomach aches, hives, and enlarged airways. Severe responses can put your life at risk. Antihistamines are used to treat minor allergic responses. A severe allergic reaction necessitates the injection of the medication epinephrine as well as emergency hospital treatment.

Apart from avoidance and injectable epinephrine for the treatment of acute allergic reactions, food allergy is a potentially life-threatening illness with no approved treatments.

What is oral immunotherapy for food allergy?

Oral immunotherapy (OIT) involves gradually increasing the amount of an allergen fed to an allergic person in order to raise the threshold at which a reaction occurs. A person allergic to peanuts, for example, might be given very little amounts of peanut protein that do not cause a reaction. Over the course of months, this modest dose is gradually increased in the allergist's office or in a clinical study environment. The purpose of therapy is to raise the threshold that can cause a reaction while also protecting the allergic person from inadvertently ingesting the allergen. OIT is not a cure-all treatment. Individuals who receive OIT will continue to carry epinephrine, read labels carefully, and so on, and it is unlikely that OIT will result in unrestricted ingestion of the allergen.

How effective is OIT?

In clinical studies, efficacy is usually measured by the induction of a desensitized state. "Desensitization" refers to the improvement in food challenge results following therapy and is dependent on continued allergen exposure. OIT with peanuts, eggs, and milk has been proven to desensitize 60 to 80 percent of

patients. Other foods' desensitization rates have not been researched as thoroughly, and some evidence suggests that OIT may not be equally effective for all food allergies. It's worth noting that, whereas efficacy has been determined in trials using oral food challenges, it's still unclear whether desensitization can protect patients from real-world accidental exposures (e.g. prevent hospitalization or death).

Some research has looked into "sustained unresponsiveness," which refers to the preservation of the protective advantage obtained through therapy that is not dependent on continued exposure. Sustained unresponsiveness hasn't been examined thoroughly enough to produce conclusive facts. Although a number of variables make broad interpretation of this data difficult, including the age of participants in the studies, length of time on therapy, and length of time off therapy at the time the sustained unresponsiveness was assessed, peanut and milk OIT have been reported to induce sustained unresponsiveness in approximately 30 to 70 percent of individuals. The majority of people who get OIT or EPIT are expected to need ongoing exposure because the therapies, in their current form, are unlikely to create a durable, long-term immunologic change.

What are the negative consequences of OIT?

The gastrointestinal (GI) tract is the most common side effect. Abdominal pain, vomiting, and cramping are common symptoms. Eosinophilic esophagitis (EoE) is an allergic condition of the oesophagus that causes difficulties swallowing, vomiting, and stomach pain in some individuals, however it is not always obvious that the therapy caused EoE. When therapy is stopped, EoE usually goes away. Oral irritation, rash, hives, edema, wheezing, and anaphylaxis are all typical side effects.

What is the current standard of care for food allergy treatment?

The current guideline for food allergy treatment is to avoid the allergen and treat anaphylaxis with auto-injectable epinephrine. While many food allergy treatments, such as OIT and epicutaneous immunotherapy (EPIT, or a skin patch), have been deemed experimental by professional allergy societies and other

Correspondence to: Neeraj Dutta, Centre for Advanced Studies, Dr. A.P.J. Abdul Kalam Technical University, Lucknow, India, E-mail: duttaneeraj24@gmail.com

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key stakeholders, the US Food and Drug Administration (FDA) approved PALFORZIATM [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp], a standardized oral immunotherapy (OIT) product for peanut allergy, on January 31, 2020. It is intended for the prevention of allergic responses, including anaphylaxis, that may develop in individuals aged 4 to 17 years old who have

a confirmed diagnosis of peanut allergy. PALFORZIA can only be obtained through a Risk Evaluation and Mitigation Strategy, according to the FDA (REMS). PALFORZIA should be taken in conjunction with a peanut-free diet and is not recommended for people who have uncontrolled asthma, eosinophilic esophagitis, or other eosinophilic gastrointestinal disorders.