

Food Allergy Immunotherapy Clinic



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Outline



1. Food allergy immunotherapy basics
2. Oral immunotherapy (OIT) efficacy and side effects
3. Is OIT the right treatment for my child?
4. What to expect with OIT treatment
5. How to add your child to the OIT waitlist
6. Research and Support for the Food Allergy Center

What is Food Allergy Immunotherapy?



- **A form of desensitization**
 - Giving small amounts of an allergen over time to try and make the body less reactive to it

- **How it is given:**

- Oral – taken by mouth
- Epicutaneous – worn as a patch
- Sublingual – placed under the tongue



Why Consider OIT?



- To prevent or decrease the severity of allergic reactions after accidental ingestion.
- To feel more comfortable with “may contain” labeling on packaged foods.
- To feel more comfortable eating at restaurants or in other social settings.

What OIT is NOT



- **Not a cure.**
 - Protection most often goes away when therapy is stopped.
- **Not to allow the food to be eaten in unlimited amounts.**
 - Strict avoidance is still advised.
- **Not to forgo carrying epinephrine auto-injectors.**
 - Emergency medications still need to be carried at all times.

FDA-approved OIT



- The U.S. Food and Drug Administration (FDA) recently approved Palförzia, a standardized OIT for peanut allergy for patients 4-17 years of age.

FDA NEWS RELEASE

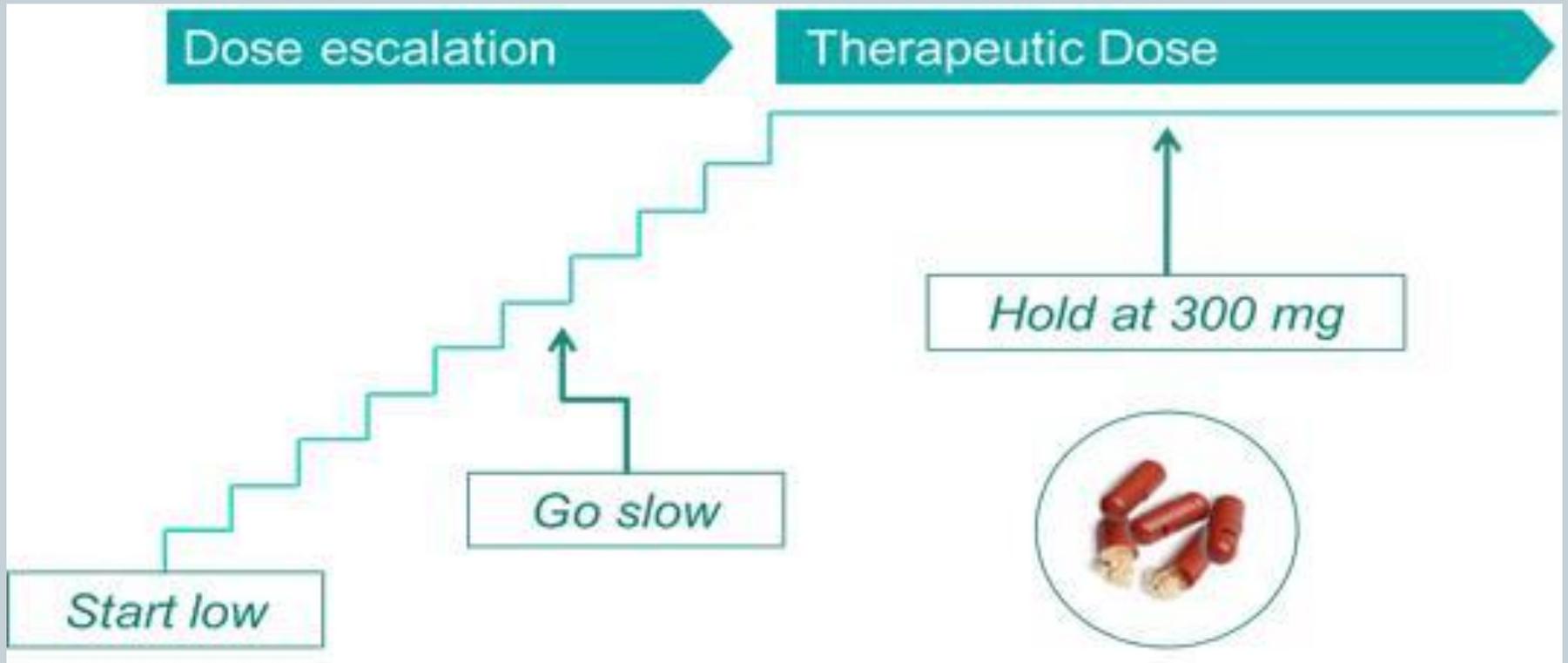
FDA approves first drug for treatment of peanut allergy for children

For Immediate Release: January 31, 2020

Palförzia[™]
Peanut (*Arachis hypogaea*)
Allergen Powder-dnfp



Basic OIT Treatment Plan

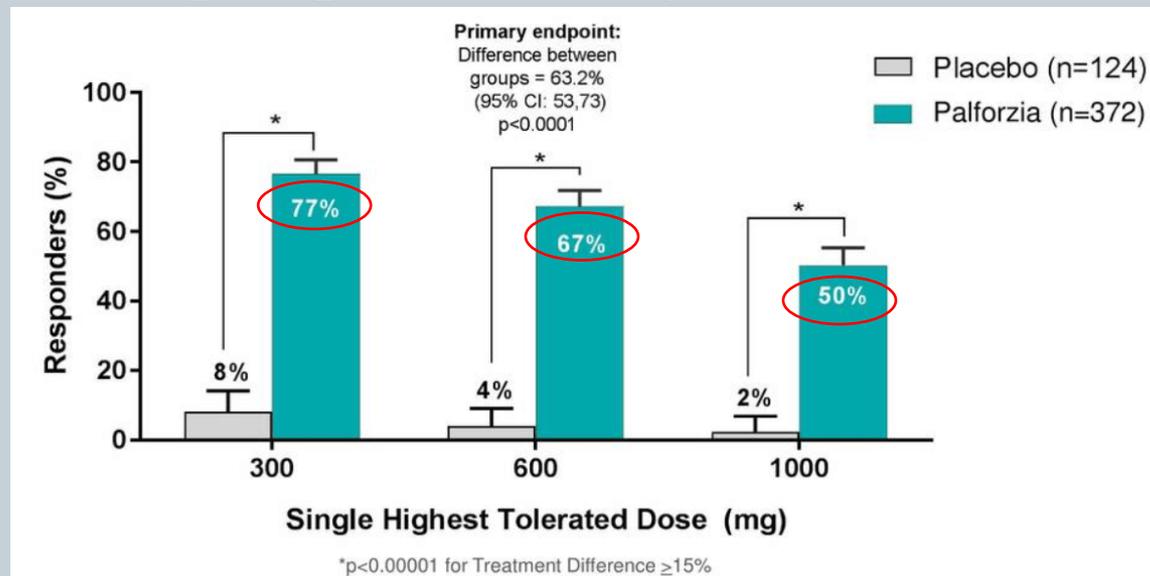


300 mg = 1 peanut

How Effective is OIT?



- In the Palforzia group, 77% tolerated $\sim 1\frac{1}{2}$ peanuts, 67% tolerated $\sim 3\frac{1}{2}$ peanuts, and 50% tolerated ~ 7 peanuts during the end-of-study challenge.
- Those on Palforzia had milder symptoms and were less likely to need epinephrine if they had a reaction.



Side Effects



- Most patients will experience mild side effects.
 - Most frequently: mouth itching, throat itching, mild abdominal pain/cramping and mild rash. Often these symptoms resolve on their own without medication or are treated with an antihistamine.
- <5% of patients in the studies experienced more severe symptoms requiring epinephrine.
 - For example: severe abdominal pain, vomiting, difficulty breathing, or wheezing.
 - Anaphylaxis is possible but uncommon.

Eosinophilic Esophagitis (EoE)



- Infrequently, patients can experience symptoms of an allergic condition called eosinophilic esophagitis.
- This condition can cause chronic abdominal symptoms (nausea, cramping, vomiting, abdominal pain) and difficulty swallowing.
- These symptoms typically go away when OIT is stopped, but it may require an evaluation by a gastroenterologist.

Is OIT the Right Therapy for My Child?



Yes

- Some anxiety about accidental ingestions.
- Child age 4-17 yrs who is interested and willing
- All parents/guardians are motivated and able to participate in therapy
- Able to attend frequent clinic visits
- Limitations on pre- and post-dose activities are acceptable

No

- Child or parent/guardian with extreme anxiety about ingesting the allergen
- Hesitation to use epinephrine auto-injector
- History of life-threatening food allergic reaction
- Other medical conditions (particularly asthma) unstable or not under control

Palforzia Protocol



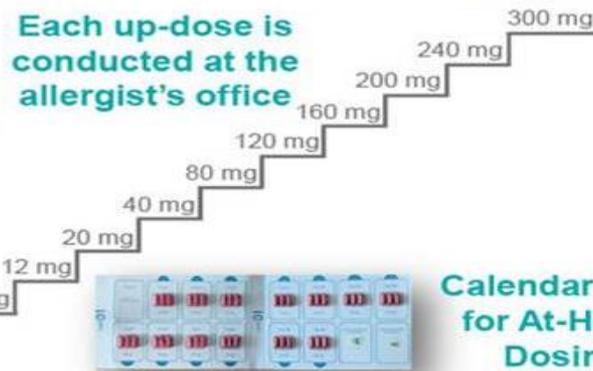
Up-Dosing Phase ~6 Months

Ongoing Maintenance



Each up-dose is conducted at the allergist's office

Initial Escalation



Calendar Pack for At-Home Dosing



300 mg Sachets for At-Home Daily Maintenance Dosing



- Start at a low dose (~1/500th of a peanut)
- Time between steps-ups is two weeks or longer based on individual needs
- Dosing flexibility allowed to accommodate individual and family needs

➤ The first dose of each increased amount is always done in the office to monitor the patient for symptoms.

Up-Dosing Phase



- The up-dosing phase is the most intensive part of the therapy and takes about 6 months.
 - Visits every 2 weeks
 - Illnesses, vacations, side effects can prolong this phase
- Each new dose requires observation for a minimum of 60 minutes
 - Visits typically last 2 hours
- Once reaching maintenance dose of ~1 peanut/day, the child's progress is monitored once every 2-6 months.

What Happens at Office Visits?



- Evaluation by the Nurse Practitioner or Doctor
- If safe to proceed, the dose is given and the patient is observed in the office.
- If symptoms develop during the visit, medications are used to stop the reaction if needed.
- Periodic skin testing and lab work will be performed to monitor the patient's allergies.

Office Visits During COVID-19



- Health screenings at all entrances
 - Temperature check
 - Symptoms, travel, and exposure
- Face coverings
- Social distancing
- Limit 1 caregiver per patient
- Please also see:
 - Visiting Guidelines www.rchsd.org/patients-visitors/
 - Videos <https://vimeo.com/rchsd>
 - ✦ Prep for Kids - COVID-19
 - ✦ Health Screeners



*Currently, through COVID Collaborative for Children, nasal swab testing is available for all patients and parents at every clinic visit

Home Doses



- If the patient tolerates the dose in the office, they then take the dose the following day and every day until their next visit.
- The capsules or sachets are opened and mixed in a semi-solid food (such as yogurt, pudding, or applesauce), and ingested in total.
- The dose should be taken around the same time every day with a meal.
 - Avoid exercise and heat exposure around time of dose

Dose Adjustments



- If the patient is sick, the dose may be held or decreased temporarily
- If the patient is having side effects or misses doses, the dose may need to be adjusted or discontinued.
- Dose adjustments may require extra clinic visits to be taken under medical supervision

Maintenance Phase



- Once the patient is tolerating their maintenance dose, the visits space out to about once every 2 to 3 months.
- These visits only require observation for approximately 30 minutes following the patient's dose if there are no symptoms, so they are shorter in length.



Length of OIT



- Currently OIT is not considered a cure.
- Research is ongoing about what happens after OIT is stopped.
- At this time, a maintenance dose will have to be taken daily indefinitely to maintain protection.

Personalized Care



- Customized treatment plan
- Experienced team to offer guidance and support each step of the way
- After hours and weekend assistance available
- Supportive community that understands the challenges of living with a food allergy
- Long-term care and support

Next Steps If You Are Interested in OIT



- Initial evaluation by one of the allergists at Rady Children's Hospital
- If your child is already a patient, add them to the waitlist for an OIT consultation visit by filling out the form at <https://www.rchsd.org/oit-waitlist>
- For more information about Rady Children's Food Allergy Center and Immunotherapy Clinic, please visit our website.

Research Opportunities



- Peanut allergy age 1-3 years
 - Peanut epicutaneous (patch) immunotherapy
 - Peanut oral immunotherapy
 - Peanut allergy with multiple food allergies
 - OIT for up to 3 foods simultaneously
 - Your child may qualify if they are at least 6 years of age and have peanut allergy and one of the following allergies: milk, egg, almond, cashew, hazelnut, walnut, sesame, fish, shellfish, wheat, or soy
- If interested, email: foodallergyresearch@rchsd.org

Supporting the Food Allergy Center



Our vision is to be a leader in advancing food allergy treatment and take part in the discovery of a cure through outstanding patient care, innovative research, education, and advocacy.



If you or anyone you know would like to learn more about the ways to support these efforts, please contact Lauren Neiman, Grateful Family Philanthropy Officer, at 858-966-8967 or lneiman@rchsd.org.