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UNC FOOD ALLERGY INITIATIVE NEWSLETTER



The FAI group is always seeking research participants to further knowledge about food allergy and allergic diseases! If you're not sure whether research is the right fit for you or your child, please visit our FAI website to learn more. You can read about our past and current clinical trials, meet our team of researchers, and register yourself or your child in our database by clicking this icon here or on our website. This tool enables us to contact you about research opportunities that may be a good fit for you or your child.

In particular, two CoFAR (Consortium of Food Allergy Research) studies continue with ongoing enrollment. The SUNBEAM study is a large, multi-center, observational, birth cohort looking at the biology of early atopy. Participation begins in pregnancy, and the child is followed from birth to 3 years.



The OUtMATCH study continues enrollment for participants 1-55 years of age. Its objective is to determine if omalizumab (Xolair) alone or combined with multi-OIT may help people with multiple food allergies. This study requires injections and OIT visits at our study center.



Additionally, we have just begun recruitment for a clinical trial, sponsored by Novartis, to assess the safety and efficacy of ligelizumab in patients with food allergy. This study involves injections at our study center, but does not require OIT dosing. Current enrollment is for peanut allergic adolescents and adults (ages 12-55). Later in the year, we will be recruiting children as young as age 6.



Welcoming Dr. Yamini Virkud to UNC!

Dr. Virkud joins UNC as a Pediatric Allergist/Immunologist and Assistant Professor at UNC Chapel Hill. She is also adjunct faculty at Massachusetts General Hospital, Boston, MA and an associate epidemiologist at the Channing Division of Network Medicine, Brigham & Women's Hospital.

Dr. Virkud will work closely with the Food Allergy Initiative as well research interests focusing on the phenotyping different patients with food allergy and understanding the mechanisms of investigational therapies for food allergy. Areas of active investigation include (1) safety of investigational therapies such as oral immunotherapy and predicting which patients are most likely to benefit, (2) studying metabolite and RNA profiles of patients with food allergy, (3) investigating the early onset of IgE mediated and non-IgE mediated

disease, like cow's milk protein intolerance, in collaboration with the Gastrointestinal Microbiome and Allergic Proctocolitis (GMAP) Study, a healthy infant cohort, (4) developing improved transitional programs to prepare adolescents to navigate adulthood with food allergies.



Prior to coming to UNC, Dr. Virkud completed her residency in pediatrics at St. Louis Children's Hospital. She trained at Duke University for her fellowship in Allergy and Immunology, where she researched under the mentorship of Dr. Wesley Burks, exploring the safety of peanut oral immunotherapy for food allergy. During this time, she also completed a clinical research fellowship at Duke Clinical Research Institute and a Masters of Public Health in Biostatistics at the University of North Carolina-Chapel Hill. From 2014-2021, she was a faculty member at Massachusetts General Hospital (MGH) and Harvard Medical School, and became the Director of Biostatistics and Data Management core of the MGH Food Allergy Center. There she conducted research on the omics of food allergic responses to oral immunotherapy, under the mentorship of Dr. Wayne Shreffler and Dr. Jessica Lasky-Su at the Channing Division of Network Medicine, Brigham & Women's Hospital. In 2021, she joined the UNC Food Allergy Initiative. She is also an investigator in the Consortium for Food Allergy Research (COFAR) and the Food Allergy Science Initiative (FASI) at the Broad Institute.

Targeting Inhibitory Siglec-3 In-Vitro to Suppress Peanut-Induced Human Basophil Degranulation

Suzanne Barshow, MD, a Duke third-year allergy and immunology fellow and member of the Kulis lab, presented an oral abstract on her research project entitled "Targeting Inhibitory Siglec-3 In-Vitro to Suppress Peanut-Induced Human Basophil Degranulation" at the recent AAAAI Annual Meeting in Phoenix, AZ. CD33 (Siglec-3) is a cell-surface receptor expressed on mast cells and basophils that recognizes sialic acid-containing glycoproteins and glycolipids and inhibits cellular signaling through immunoreceptor tyrosine-based inhibitory motifs (ITIMs). Our colleagues in the James Paulson, PhD lab at Scripps Research in La Jolla, CA have directly conjugated monoclonal anti-IgE to human CD33L with the goal to recruit CD33 to the high-affinity IgE receptor complex and inhibit IgE-mediated mast cell and basophil activation. By pretreating human basophils in-vitro with the anti-IgE-CD33L direct conjugate, Dr. Barshow has been able to suppress basophil activation to whole peanut extract in a model of peanut allergy. Next steps will demonstrate the broader applicability of this molecule to inhibit antigen non-specific allergic activation of basophils through stimulation with non-blocking polyclonal anti-IgE."



Pigs lacking alpha-gal take center stage

Researchers at the UNC FAI focus on patients with an allergy to alpha-gal; however, all humans make a non-allergic response to the alpha-gal sugar. Because mammals such as cows and pigs have alpha-gal, it has been impossible to transplant organs from these animals into humans due to hyperacute rejection that occurs from the non-allergic response to alpha-gal. Now enter pigs without alpha-gal. These pigs were approved by the FDA last year and what followed has made headlines: two patients each received a kidney from the alpha-gal deficient pigs and another person received a “Gal-safe” heart. The patients all lived additional weeks, actually an additional 2 months for the patient receiving the heart.

These few transplants were the initial ones and we anticipate additional cases to follow. Pending availability, these pigs will be the source of alpha-gal-free pork and materials for other porcine-derived medical/surgical products, such as surgical mesh and heart valves, for patients with alpha-gal allergy. Recent publications have linked alpha-gal responses with heart disease and atherosclerosis, raising the question of whether the alpha-gal deficient pigs might be more widely important for limiting cardiovascular disease in all humans. For now, we are focused on doing food challenges with alpha-gal-free pork in patients allergic to alpha-gal



Peanut anaphylaxis in 2022 – Decoupling epinephrine usage from emergency department evaluation

Dr. Andrew Winslow M.D. along with co-investigators Deanna Hamilton RN, and Dr. Edwin Kim M.D., M.S. analyzed existing data the UNC Food Allergy Initiative and sought to explore patterns of epinephrine usage and the frequency of biphasic anaphylaxis among a high-risk peanut allergy cohort seeking entry into three clinical trials taking place from 2011-2017. Much in the same fashion as many other interventional clinical trials for food allergy, these peanut allergic participants required both a clinical history of peanut allergy and elevated biomarkers reflecting allergic sensitization to peanut (median SPT 13 mm and median sIgE 61.6 kUA/L). Further, participants were required to react during ‘entry food challenges,’ to permit trial entry prior to the usage of any interventional therapy. Investigators analyzed a total of 113 entry double-blind placebo-controlled oral food challenges to peanut; while each patient demonstrated IgE-mediated food allergy symptoms during entry food challenges, only a subset of patients (44 cases, 39%) had more severe symptoms qualifying as anaphylaxis, via strict application of NIAID/FAAN criteria. For these patients, treatment with epinephrine was administered a median 5 minutes after anaphylaxis onset. Investigators identified just a single instance of biphasic anaphylaxis (0.9%) among all patients, which required complete resolution of symptoms and then re-emergence of anaphylaxis symptoms in 1-48 hours, in the absence of an additional anaphylaxis trigger. No cases of persistent or refractory anaphylaxis were identified. Our experiences from the UNC Food Allergy Initiative lend support to the rare incidence of biphasic anaphylaxis, even among the most highly peanut-allergic cohort.

Given the added emphasis on reducing reflexive healthcare utilization during the COVID-19 pandemic, the investigators are excited to share this research with food allergy stakeholders and with patients alike, to help promote a more targeted message – that seeking emergency medical care for the purposes of ongoing monitoring is not mandatory in the case of appropriate response to timely treatment of food-triggered anaphylaxis with epinephrine, provided no risk factors for biphasic anaphylaxis are identified and access to appropriate post-reaction care can be ensured. Dr. Winslow recently presented these findings at the 2022 AAAAI Annual Meeting in Phoenix, AZ, and has submitted the work for hopeful publication.

Early Peanut Oral Immunotherapy Shows Strong Efficacy and the Potential for Remission

One of the most significant advances in food allergy has been the 2015 LEAP study which showed us that introducing peanut in infancy can dramatically reduce the rate of peanut allergy. It pointed to there being a key window of time when the immune system might be most able to change course in a child who otherwise might be at high risk to develop peanut allergy. With this in mind, researchers at the UNC FAI and other food allergy centers across the country wondered whether younger age could provide a similar advantage when treating peanut-allergic children with oral immunotherapy (OIT).

The NIH and Immune Tolerance Network sponsored IMPACT study was designed to answer this question by looking at the effects of peanut OIT in young 1-4 year old toddlers. IMPACT was a multi-center, randomized, controlled study conducted across 5 US sites (Arkansas Childrens, Johns Hopkins, Mt Sinai, Stanford, UNC) and led by our team at the University of North Carolina. Participants underwent a baseline food challenge to establish their baseline threshold of peanut, then were treated with 2000 mg of peanut OIT (~ 7 peanuts) daily for 25 years. A second food challenge showed how high of a threshold they were desensitized to, and then they were instructed to avoid all peanut for 6 months followed by a final food challenge with a goal of showing how long lasting the treatment effect could be.



The results of the IMPACT study were published by Stacie Jones (Arkansas Childrens) and Edwin Kim (UNC FAI) in the January 2022 of The Lancet. The results showed that 71% of peanut-allergic toddlers could safely eat 5000 mg of peanut protein after OIT compared to only 1 toddler (2%) on placebo. After stopping all peanut for 6 months, 21% of the OIT group still safely ate the full 5000 mg showing a remission of their peanut allergy. In the placebo group, only the 1 toddler (2%) again passed the food challenge showing that he likely naturally outgrew his allergy. Safety with the treatment was similar to prior OIT studies with side effects being common but mostly mild and moderate.

With more children being introduced to peanut early, we anticipate preventing a lot of peanut allergy. At the same time, we would also expect to be diagnosing peanut allergy at a younger age as well. The results of the IMPACT study show that peanut OIT can be done in young toddlers with safety that is manageable. Importantly, it showed the strongest desensitization levels to date and even the possibility of a long-term remission in a subset of the kids that could change the way we manage peanut allergy moving forward. For more coverage of the study please see...

[In Toddlers, OIT Can Lead to Peanut Allergy Remission, Study Finds](#)

[Oral immunotherapy may lead to remission of peanut allergy in young children](#)

[Peanut Oral Immunotherapy Is Safe and Effective in Toddlers in Large Placebo-Controlled Trial](#)

[Oral Immunotherapy Alleviates Peanut Allergy in Some Young Children](#)

PEDIATRIC ALLERGY & IMMUNOLOGY CLINIC



Our Pediatric Allergy & Immunology team has the following providers seeing new and return patients at our Chapel Hill location:

Sarah Bennick, CPNP
Samantha Borden, CPNP
Emily English, CPNP
Lauren Herlihy, CPNP
Corinne Keet, MD
Edwin Kim, MD
Yamini Virkud, MD

Please call 984-974-1401 to schedule an appointment at Carolina Pointe II (6013 Farrington Road, Suite 201) at the intersection of I-40 and Hwy 54.