Press Release

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Protection against peanut allergy by early consumption persists following a one-year period of peanut avoidance

WA, Seattle (March 4, 2016) **–** Peanut allergy prevention achieved from early peanut consumption in at-risk infants persists after a one-year period of avoiding peanut, a clinical trial has found. The LEAP-ON clinical trial (Persistence of Oral Tolerance to Peanut) was conducted by the Immune Tolerance Network (ITN), a research consortium supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and led by Dr. Gideon Lack from Kings College London. The results were published today in the *New England Journal of Medicine*.

The LEAP-ON study was an extension of the ITN's landmark LEAP Study (Learning Early About Peanut Allergy), which demonstrated that regular peanut consumption begun in early infancy and continued until age 5 reduced the rate of peanut allergy in at-risk infants by 80% compared to non-peanut-consumers. LEAP was the first large, well-controlled study to conclusively show the benefits of early peanut consumption in this population, changing previous notions about peanut allergy prevention.

However, LEAP did not answer the question of whether participants who had consumed peanut for more than four years were protected long-term against peanut allergy when they stopped eating peanut.

To examine this question, the LEAP-ON study followed 556 of the original 640 children in LEAP (both consumers and avoiders) for a one-year period of peanut avoidance. This cohort included 274 previous peanut consumers and 282 previous peanut avoiders. Compliance with peanut avoidance was assessed by a validated questionnaire and was confirmed by quantifying peanut protein in dust samples collected from participants' beds. Allergy status was determined using an oral food challenge at the end of the study.

After 12 months of peanut avoidance, only 4.8% of the original peanut consumers were found to be allergic, compared to 18.6% of the original peanut avoiders, a highly significant difference.

"The LEAP-ON findings exceeded our expectations and demonstrated that the early consumption of peanuts provided stable and sustained protection against the development of peanut allergy in children at greatest risk for this allergy," Dr. Lack pointed out. "This protective effect occurred irrespective of whether the children completely avoided peanut for one year or continued to eat it sporadically."

The persistence of tolerance with complete avoidance of peanut for one year strongly suggests that periodic lapses in peanut consumption will not cause a reemergence of allergy.

Whether tolerance will decline after longer periods of avoidance is not known, and the investigators are planning longer-term follow-up of the study participants.

“This study offers reassurance that eating peanut-containing foods as part of a normal diet—with occasional periods of time without peanut—will be a safe practice for most children following successful tolerance therapy,” said Dr. Gerald Nepom, Director of the Immune Tolerance Network. “The immune system appears to remember and sustain its tolerant state, even without continuous regular exposure to peanuts.”

Datasets and figures from both the LEAP and LEAP-ON published manuscripts (including de-identified participant-level data) are available to the public on the ITN’s clinical research portal, TrialShare. The community is encouraged to use this rich data resource to perform novel exploratory analyses and generate new hypotheses about peanut allergy.

“We are grateful to the children and their families who participated in this important trial,” said Dr. Lack. “We believe this new information will inform the public health debate on infant guidelines and shed light on the mechanisms that underpin the induction of oral tolerance."

About The Immune Tolerance Network

The Immune Tolerance Network (ITN) is a research consortium sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health. The ITN develops and conducts clinical and mechanistic studies of immune tolerance therapies designed to prevent disease-causing immune responses, without compromising the natural protective properties of the immune system. Visit www.immunetolerance.org for more information.

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