

Study Protocol

Official Title: Immunological Response After Shrimp Oral Immunotherapy Treatment

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Sponsor: Mahidol University / Siriraj Hospital

Background

Shrimp allergy is a major cause of food-induced anaphylaxis in Asia. Current management relies on strict avoidance and emergency treatment, but this strategy does not modify the underlying immune response. Oral immunotherapy (OIT) has emerged as a potential disease-modifying treatment that may increase clinical reaction thresholds and induce immunologic tolerance.

Objective

To evaluate the clinical efficacy, immunologic effects, and safety of shrimp oral immunotherapy compared with strict avoidance in participants with confirmed shrimp allergy.

Study Design

Single-center, open-label randomized controlled trial conducted at Siriraj Hospital, Bangkok, Thailand. Participants were randomly assigned in a 1:1 ratio to receive shrimp oral immunotherapy (OIT) or strict avoidance.

Participants

Eligible participants were aged 12–40 years with documented immediate allergic reactions to shrimp, positive skin prick testing or shrimp-specific IgE (≥ 0.35 kUA/L), and a positive oral food challenge (OFC) to *Litopenaeus vannamei*.

Intervention

Participants in the intervention arm received shrimp oral immunotherapy with dose escalation every four weeks until reaching a maintenance dose of approximately 20 grams of shrimp. The avoidance group was instructed to avoid shrimp and other shellfish throughout the study period.

Primary Outcome

Change in eliciting dose (ED) of shrimp during oral food challenge from baseline to 12 months.

Secondary Outcomes

Secondary outcomes include changes in shrimp-specific IgE and IgG4 levels, component-resolved allergen responses, skin test reactivity, and adverse events associated with shrimp oral immunotherapy.

Statistical Analysis

Continuous variables are summarized as median and interquartile range (IQR). Differences between groups are analyzed using Wilcoxon rank-sum tests for continuous variables and Chi-square or Fisher's exact tests for categorical variables. Statistical significance is defined as $P < 0.05$.