

Boiled Tree Nut for Oral Immunotherapy in Food-allergic Children

NCT06467994

Status	RECRUITING
Phase	Phase 2
Sponsor	Chinese University of Hong Kong
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (5)

- Aged between 3 year and 17 years of age;
- Either sex, and of any race and ethnicity;
- ≥ 7 kg (the weight considered safe for the administration of an adrenaline autoinjector) (e.g. Jext);
- Confirmed diagnosis of cashew nut allergy as defined by a failed DBPCFC with cashew nut and a positive SPT (≥ 3 mm than control) or sIgE to cashew nut (of at least 0.35 kUA) at screening.
- Subject's parent and/ or guardian must be able to understand and provide informed consent.

Exclusion (14)

- History of severe anaphylaxis (as defined by persistent hypotension, collapse, loss of consciousness, persistent hypoxia or ever needing more than three (3) doses of intramuscular adrenaline or an intravenous adrenaline infusion for management of an allergic reaction)
- Severe anaphylaxis during the study entry DBPCFC (defined as persistent hypotension, collapse, loss of consciousness, persistent hypoxia, or requiring more than 3 doses of intramuscular adrenaline or an intravenous adrenaline infusion for management of an allergic reaction)
- Any disorder in which adrenaline is contraindicated (such as hypertension or cardiac rhythm disorders)
- Reacting to the placebo component during the study entry DBPCFC
- FEV1 $< 85\%$ at rest and FEV1/FVC $\geq 85\%$ at rest or ongoing chronic persistent asthma (as per Australian Asthma Foundation guidelines)
- ... and 9 more (see full listing online)

Locations (1 total)

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