OLVG Food Allergy Growth Study

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25057

Source
NTR

Brief title
Growth studie

Health condition

Food allergy

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Nutricia Research

Intervention

Outcome measures

Primary outcome

Height-for-age: Most recent height/length, head circumference and weight are derived from the medical record, using calibrated digital scales, length board or height board and a non-stretchable tape measure measured by medical staff during routine medical visits at the paediatric departments OLVG Oost and West.

Secondary outcome

Within 4 weeks after handing in signed informed consent:
• Weight-for-height, weight-for-age, and BMI SDS are calculated using ethnic adjusted standard deviation scores (SDS) by the study dietitian Mooij-Nieberg, which will be obtained by using Dutch growth standards (3,20) as well as the standards provided by the World Health Organisation for growth (18,19);
• The association between patient characteristics and possible contributing factors for poor growth; Patient characteristics and risk factors will be obtained by the study dietitian Mooij-Nieberg, using telephone questionnaires as pointed out in 3.5.2;
• The association between calprotectin and growth; A stool sample will be collected at home and sent to OLVG hospital. Calprotectin will be analyzed In batches at Hanze University of Applied Sciences, department of Life Sciences, as pointed out In 3.5.3.;
• The association between calprotectin and growth in children with diagnosed food allergies; Patients or their caregivers will fill in 3x an online 24-hour recall diary about all foods and drinks consumed. These will be checked for completeness by the study dietitian Mooij-Nieberg.

Study description

Background summary

International Survey on Growth in Children with Food Allergies with unexpected finding for OLVG
Recently, the department of Pediatrics of the OLVG participated in an international survey on growth in children with food allergies, initiated by Dr. Rosan Meyer, Imperial College, London. The purpose of this survey was to establish growth of children with food allergies and factors that impact on growth from allergy centers across the world. Surprisingly, it was found that the Dutch children had the lowest height-for-age z-score, while the Dutch people are the tallest in Europe.
The lower height-for-age-scores in the Dutch children may be (partly) explained by 1. Ethnic background of the study population, 2. High percentage of non-IgE mediated and mixed food allergy, 3. Lack of dietetic counseling on elimination diets, resulting in low energy and/or nutrient deficiencies (although in not all countries dietitians were involved), and 4. Ongoing inflammation due to the allergic status of the children.
Poor growth data in food allergy is frequently reported in the literature according to a recently published review on growth in food allergic children. It was concluded that children with food allergies often have poorer growth parameters than the general population. Risk factors for poor growth are atopic dermatitis and cow’s milk allergy. Nutritional deficiencies are frequently found, in particular calcium and vitamin D, but also low serum levels of zinc, iron, B vitamins and deranged fatty acids have been found.
To our knowledge no other data have been published on growth in food allergic children in the Netherlands.

AIM: To overall aim of the OLVG GROWTH STUDY is to study growth in food allergic children 0-18 years at OLVG, taking into account target height, ethnicity, nutrition intake and other

risk factors.
Methods:
1. In all patients length and weight will be measured during routine out-clinic hospital visits.
In addition to the routine care, within 4 weeks after signing informed consent:
2. Patient characteristics will be collected from the medical record;
3. Patients will be interviewed about possible contributing factors to poor growth, either on location or by telephone;
4. Patients will collect 2 stool samples, which will be collected at home and returned by mail to OLVG;
5. Sixty patients will fill in 3x an online 24-hour recall diary about all foods and drinks consumed;
6. Sixty patients will be asked if to give consent for being contacted by the researchers in a follow-up study for a blood sample (inflammation markers, status of relevant vitamins or minerals, such as calcium, vitamin D, iron, vitamin B6, folic acid), microbiome analysis in the spare stool sample, and personal growth charts via the Preventive Child Healthcare centers.
Total duration of project: 12 months
Starting date: 1 November 2020
End date: 31 October 2021

Study objective

Risk factors for poor growth in food allergic children are ongoing inflammation caused by atopic dermatitis, food allergy and possibly low energy and nutrient intakes.

Study design

Within 4 weeks after handing in signed informed consent:
Primary outcome
Height-for-age:l ength board or height board
Secondary outcomes:
Weight-for-height and weight-for-age SDS: calibrated digital scales, Dutch growth standards, WHO growth standards
BMI: l (cm)/g (kg)2
risk factors: telephone questionnaire
calprotectin: stool sample
nutritional intake: 3 online 24-hour recalls

Intervention

none

Contacts

Public

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Eligibility criteria

Inclusion criteria

Any child between 0-18 years of age with a confirmed food allergy and elimination diet:
1. Confirmed through either skin prick testing/specific IgE testing which has led to a recommendation for the elimination of these allergens from the diet;
2. Confirmed through a food challenge;
3. Confirmed through an elimination diet followed by re-introduction at home ;
4. Children born à term (between 37 and 42 weeks of gestation).

Exclusion criteria

1. Children with non-allergic co-morbidities – Down’s Syndrome, cerebral palsy etcetera;
2. Children where it is not possible to measure growth parameters;
3. Children where food allergies have not been confirmed;
4. Not able to speak and write in Dutch or English properly;
5. Preterm children: birth before 37 weeks of gestation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9166
Other	ACWO OLVG : WO20.216

Study results