The need for comparison of oral food challenge outcomes: the ALlergy Diagnosed by Open oR Double blind food challenge (ALDORADO) trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27959

Source
Nationaal Trial Register

Brief title
ALDORADO

Health condition

Food allergy

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Nutricia Wetenschapsinstituut Martini Ziekenhuis

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the difference in the proportion of positive outcomes of the DBPCFC and the open food challenge.

Secondary outcome

The following secondary outcome measures will be analysed: eliciting dose (i.e. first dose that causes allergic symptoms) and stopping dose (i.e. cumulative total dose that has been eaten), occurrence and severity of symptoms on all challenge days as well as the percentage of false positive reactions (i.e. the occurrence of allergic symptoms on placebo day in case of DBPCFC).

Study description

Background summary

It is of major importance to diagnose food allergy accurately. Current guidelines support the use of oral food challenges to do so. The double-blind placebo controlled food challenge (DBPCFC) has been regarded as the “gold standard” for decades. However, DBPCFCs are costly, time- and resource intensive procedures. Structural implementation of less demanding open food challenges will only find support if research demonstrates that their outcome will be comparable to DBPCFC, yet this has been proven difficult to investigate. This non-inferiority study has been set up to address the research question to investigate if open food challenges are comparable to DBPCFC in children suspected of having food allergy for cashew nut, hazelnut or peanut.

Study objective

We hypothesise that the open food challenge is comparable to the “gold standard” DBPCFC in children suspected of having food allergy for cashew nut, hazelnut or peanut.

Study design

Participants will undergo both challenges for the specific potential food allergen. We will always start with the DBPCFC, followed by the open food challenge. Furthermore, the DBPCFC outcome will be kept blinded until the last challenge has been performed. Parents will be instructed not to introduce the food into their child’s diet until the last and final test has been performed. We defined unequivocal criteria to decide whether the OFC can be continued in case of (severe) symptoms. In case of an anaphylactic reaction, no further challenges will be planned. The interval between both challenges will be at least one week and no more than six weeks.

Intervention

All participants will undergo both DBPCFC and open food challenge. DBPCFC is part of usual clinical practice, the open food challenge will be extra. All challenges will be performed according to the European Academy of Allergy and Clinical Immunology (EAACI) guidelines. Prior to the OFCs, as part of usual clinical practice one blood sample will be collected to investigate whether the child is sensitised for the specific food.

Contacts

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Eligibility criteria

Inclusion criteria

Children aged 4-18 years who visit our paediatric allergy centre of the Martini Hospital and who are recommended to perform an OFC for a suspected food allergy for cashew nut, hazelnut or peanut.

Exclusion criteria

- children younger than the age of four years
- patient uses beta blockers and/or prednisolone
- patient suffers from uncontrolled asthma, unstable angina pectoris or fever
- patient reports to be pregnant
- patient is unable to adequately report the occurrence of possible symptoms (e.g. mentally disabled or not native Dutch speaker)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50961
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9533
CCMO	NL76237.000.21
OMON	NL-OMON50961

Study results