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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27959

Bron
Nationaal Trial Register

Verkorte titel
ALDORADO

Aandoening

Food allergy

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: Nutricia
Wetenschapsinstituut Martini Ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50961
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten