A virtual, decentralised observational follow-up study investigating feeding patterns in infancy and the associated parent-reported allergic manifestations, allergies and infections in childhood.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON53433

Source
ToetsingOnline

Brief title
TEMPO Follow-Up

Condition

- Allergic conditions
- Respiratory tract infections
- Angioedema and urticaria

Synonym
Allergies, infections

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Feeding Patterns, Immune-related outcomes, Observational, Virtual

Outcome measures

Primary outcome

1. The occurrence of

• parent-reported allergic manifestations (e.g. symptoms suggestive of wheeze/asthma, eczema/atopic dermatitis, allergic rhinitis/hayfever, food allergy, pet allergy, house dust mite allergy).

• parent-reported doctor*s diagnosis of asthma, allergic rhinitis/hayfever, eczema/atopic dermatitis, food allergy, pet allergy, house dust mite allergy.

• parent-reported manifestations of infections (e.g. symptoms suggestive of respiratory tract, stomach, intestines, skin and urinary infections).

• parent-reported doctor*s diagnosis of respiratory tract, stomach, intestines, skin and urinary infections.

2. The use of medications and/or a medical device (inhaler) to prevent or relieve allergic manifestations, allergies and/or infections.

3. Number of days hospitalised for allergic manifestations, allergies, and/or infections.

4. Number of visits to the emergency room for allergic manifestations, allergies, and/or infections.

Secondary outcome

N/A

Study description

Background summary

This is an follow-up study of a randomised clinical trial, called TEMPO, in which infants participated in their first year of life (a double-blind randomised clinical trial investigating infant formula and human milk consumption). Data from this TEMPO study will be re-used and linked to newly collected data from the follow-up study, called Long-term Effect of Mixed Milk Feeding study (LF effect MMF study or Tempo Follow-Up) study, that is described in this protocol. Where it reads *first year of life*, the text refers to information about the children that was previously collected in the original TEMPO study.

Study objective

Given the worldwide-observed rapid increase in the prevalence of allergic diseases, it is likely that environmental risk factors, including geographic area and lifestyle factors play a substantial role in the development of allergies and other atopic diseases. Infant nutrition is an important modifiable lifestyle factor that influences the development and maturation process of a child*s immune system, which may increase sensitization and thereby the risk of atopic diseases in childhood. Adequate nutrition is also important for the prevention of certain infections as nutrition can have an immunomodulating function and thus influence susceptibility to infections, as well as the course and outcome of the infections. The set of data of infants from different countries from the TEMPO trial provides a unique opportunity to gain further insights in the immune development of these infants beyond their first year of life. It also offers the possibility to explore relationships between recognized risk factors in allergy and immune system development (such as mode of delivery, antibiotics use), laboratory parameter levels during the first year of life and immune development (allergic manifestations, allergies and infections) thereafter. The TEMPO Follow-Up study is unique because of the existing detailed information including laboratory outcomes of the children in their first year of life, its geographical distribution, and its fully virtual and decentralised design.

Study design

TEMPO Follow-Up is a virtual and fully decentralised follow-up study of a cohort of children who completed a nutritional randomised clinical trial in infancy, called TEMPO study. It is a longitudinal prospective observational cohort study in subjects without an intervention. The study is conducted virtually using (smart)phone/computer-based subject recruitment, enrolment and collection of study data. The participants are not required to visit a physical study site and will not have any communication about their child*s health with a health care provider. In the study only parent-reported information is collected. This is done through completion of three-monthly digital questionnaires that are accessed by the parents via an application that is installed on a self-owned mobile device (smartphone or tablet) or via web-based questionnaires using a personal computer. The parents will be asked whether health outcomes such as asthma, hayfever, eczema, food allergy or certain infections were diagnosed by a doctor, however these are not reviewed or confirmed by a doctor. Also no data from medical records will be collected. The children will be followed up until they are ten years of age.

Study burden and risks

As this is an observational cohort study without an (invasive) intervention (e.g. no consumption of a study product, no bio-sampling, no intrusive questions), the study presents no health risk. A high amount of new data will be collected whilst keeping the burden of participation for the parents low by the fully virtual and decentralised design (participation from home, digital questionnaires).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Subject completed the final (12 months) visit in the TEMPO study.
- Parents agree that their contact details will be shared with a third party for study purposes.
- Parents agree that data collected in the TEMPO study will be used in the TEMPO Follow-Up study.
- Parents provide written informed consent for participation in the TEMPO Follow-Up in accordance with local law.

Exclusion criteria

- Parents who do not have a smartphone, tablet or personal computer with internet access.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2022
Enrollment:	41
Type:	Anticipated

Ethics review

Approved WMO Date:	19-10-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-02-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCTnummernognietbekend
CCMO	NL81702.100.22