Basophil Activation Test cow's milk for replacement of the food challenge test

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Determination of the (cost)effectiveness of the replacement of the expensive, risky and time-consuming food challenge test bythe Basophil Activation Test (BAT) for the diagnosis of an IgE-mediated cow*s milk allergy in children.

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

Summary

ID

NL-OMON52026

Source
ToetsingOnline

Brief title
BAT cow's milk for replacement of the food challenge test.

Condition

- Allergic conditions

Synonym
cow's milk allergy

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Veelbelovende Zorg;ZIN

Intervention

Keyword: Basophil Activatie Test, cow's milk, oral food challenge

Outcome measures

Primary outcome

The sensitivity, specificity, negative- and positive predictive value of the

BAT. Effectiveness of replacement of the food

challenge test by the BAT in diagnostic delay (and consequently quality of

life) and in costs of diagnostics and prescription of

hypoallergenic formula.

Secondary outcome

1) Cost reduction in diagnostics (replacement of the food challenge test by the

BAT) and cost reduction in prescription of

hypoallergenic formula due to reduction in diagnostic delay.

2) Effect of reduction in diagnostic delay and burden of diagnostics on patient

quality of life.

Study description

Background summary

Until now, cow*s milk allergy diagnosis is based on a food challenge test. However, this food challenge test is expensive, time consuming (2-day hospital stay), risky, stressful for children and their parents, with waiting lists of several (2-6) months. This waiting time results in unnecessarily long-term use of
expensive hypoallergenic milk formula (reimbursed by the health insurance). Therefore, there is a great need to introduce a better and faster diagnostic test for cow*s milk allergy diagnosis in standard care. The in vitro Basophil Activation Test (BAT) is cheap, quick (result < 1 day, no waiting list), safe for the child and is a reliable alternative for the food challenge test to

diagnose an IgE-mediated allergy. Although the potential added value of the BAT is known for years, this test has not been implemented in guidelines yet. This is due to the fact that more insight is required into the (cost-)effectiveness regarding a) reduction in food challenge tests, b) prescription of hypoallergenic milk formula and c) health gain due to a shorter diagnostic work-up and reduction in risky food challenge tests.

Study objective

Determination of the (cost)effectiveness of the replacement of the expensive, risky and time-consuming food challenge test by the Basophil Activation Test (BAT) for the diagnosis of an IgE-mediated cow*s milk allergy in children.

Study design

The study design is a multicentre (n=17), prospective, cohort study. In this study for all children both a BAT cow*s milk (index test) and a food challenge test (reference test) will be performed. The results of both tests are compared per individual and used for determination of the sensitivity, specificity, PPV and NPV of the BAT. Change in quality of life of child/parents due to knowledge of the allergic status of the child will be assessed by taking (Food Allergy) Quality of Life Questionnaires before and after the food challenge test. The period (in weeks) between the date of inclusion and the result of the food challenge test will be recorded and used to calculate the theoretically reduction in use of hypoallergenic cow*s milk formula.

Study burden and risks

The burden and risks of participating in this study are low as it only concerns one extra blood collection and two times completing a short questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Inclusion criteria (all criteria must be met with in b. one or more symptoms):
a. Age 0-12 years
b. Suspected of cow's milk allergy with one or more of the following complaints after intake of cow's milk:
- angioedema
- urticaria
- sneezing and rhinitis <2 hours after feeding
- sensation of swelling in the throat and/or difficulty swallowing <2 hours after feeding
- voice change/hoarseness <2 hours after feeding
- cough <2 hours after feeding
- wheezing and/or shortness of breath <2 hours after feeding
- loss of consciousness <2 hours after feeding
- vomiting or abdominal pain or diarrhoea <2 hours after feeding in children <4 years only in combination with IgE-mediated complaints in other tracts
c. Placed on a waiting list for a hospital food challenge test
d. Blood draw for cow*s milk sIgE and BAT < 3 months before the food challenge test
e. Signed informed consent parents/guardians

Exclusion criteria

Exclusion criteria (if one or more criteria are met, the child will be

excluded):
a. Age > 12 years
b. Suspicion of Food Protein-Induced Enterocolitis Syndrome (FPIES)
c. Eosinophilic esophagitis due to a cow's milk allergy
d. Suspected cow's milk allergy <4 years with crying and/or agitation and/or eczema and/or abdominal pain and/or failure to thrive and/or blood loss per anum and/or diarrhoea and/or reflux and/or vomiting as the only manifestation of the allergy without IgE-mediated symptoms in another organ system
e. Systemic immunosuppressant use
f. Other underlying chronic conditions (immunological, oncological, chromosomal abnormalities).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2022
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	13-09-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-11-2021

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL76893.091.21