

Pilotstudy: Probiotics in children with atopic dermatitis and food allergy: is there an in vivo or in vitro effect on the immunological response?

No registrations found.

| | |
|------------------------------|---------------------|
| Ethical review | Positive opinion |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON27882

Source

NTR

Brief title

N/A

Health condition

Atopic dermatitis and food allergy.

Sponsors and support

Primary sponsor: Winclove BioIndustries BV

Papaverweg 36-B

PO Box 37.239

1030 AE Amsterdam

The Netherlands

Intervention

Outcome measures

Primary outcome

Allergen-specific T cell response, B cell response.

Secondary outcome

SCORAD, IgE RAST, SPT.

Study description

Background summary

N/A

Study objective

Treatment with probiotics can alter the allergen-specific in vivo or in vitro immunological response in food-allergic children.

Study design

N/A

Intervention

Active group: 3 months treatment with a daily dose of a mixture of probiotics.

Placebo group: 3 months treatment with a daily dose of placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. 0-3 years of age;
2. Atopic dermatitis;
3. History strongly suggestive of food allergy or positive placebo-controlled food challenge;
4. IgE RAST ≥ 0.7 kU/l for at least 2 food allergens;
5. SPT $\geq 2+$ for at least 2 food allergens.

Exclusion criteria

1. Other systemic diseases;
2. Immunocompromized;
3. Systemic treatment with immunomodulating drugs.

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |

| | |
|----------|-------------------------------|
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-03-2003 |
| Enrollment: | 13 |
| Type: | Actual |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 23-08-2005 |
| Application type: | First submission |

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 | NL96 |
| NTR-old | NTR127 |
| Other | : N/A |
| ISRCTN | ISRCTN28834761 |

Study results

Summary results

Int Arch Allergy Immunol. 2007;143(3):237-44. Epub 2007 Feb 9.