

Pilot study: probiotics in children with atopic dermatitis and food allergy - is there an in vivo or in vitro effect on the immunological response?

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 06/07/2009	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR127

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, double blinded, placebo controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Food allergy, atopic dermatitis

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Probiotics

Primary outcome(s)

1. Allergen-specific T-cell response, B cell response.

Key secondary outcome(s)

1. SCORing Atopic Dermatitis (SCORAD)

2. Immunoglobulin E Radioallergosorbent Test (IgE RAST)

3. Skin Prick Test (SPT)

Completion date

01/03/2005

Eligibility

Key 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. Immunoglobulin E Radioallergosorbent Test (IgE RAST) greater than or equal to 0.7 kU/l for at least two food allergens
5. Skin Prick Test (SPT) greater than or equal to 2+ for at least two food allergens

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

0 Years

Upper age limit

3 Years

Sex

All

Key exclusion criteria

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

Date of first enrolment

01/03/2003

Date of final enrolment

01/03/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre

Dep. Dermatology/Allergology (G02.124)

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

Winclove BioIndustries BV (Netherlands)

ROR

<https://ror.org/02c0pn910>

Funder(s)

Funder type

Industry

Funder Name

Winclove BioIndustries BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2007		Yes	No