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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 [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 06/07/2009	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised, double blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. SCORing Atopic Dermatitis (SCORAD)
2. Immunoglobulin E Radioallergosorbent Test (IgE RAST)
3. Skin Prick Test (SPT)

Overall study start date
01/03/2003

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

Age group
Child

Lower age limit
0 Years

Upper age limit
3 Years

Sex
Both

Target number of participants
13

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)

Sponsor details
Papaverweg 36-B
P.O. Box 37239
Amsterdam
Netherlands
1030 AE

Sponsor type
Industry

Website
http://www.winclove.nl/

ROR
https://ror.org/02c0pn910

Funder(s)

Funder type
Industry

Funder Name
Winclove BioIndustries BV (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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