ISRCTN26134979 https://doi.org/10.1186/ISRCTN26134979

Effect of probiotics in the primary prevention of atopic eczema

Submission date	Recruitment status
25/03/2009	No longer recruiting
Registration date	**Overall study status**
27/05/2009	Completed
Last Edited	**Condition category**
10/07/2019	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Geun Eog Ji

Contact details
San 56-1, Shinlimdong
Kwanakku
Seoul
Korea, South
152-742
-
geji@snu.ac.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of probiotics (Bifidobacterium bifidum, Bifidobacterium lactis, Lactobacillus acidophilus) in the primary prevention of atopic dermatitis: a double-blind, randomised, placebo-controlled trial

Study objectives
To investigate whether prenatal and postnatal administration of a mixture of Bifidobacteria and Lactobacillus can prevent the development of atopic dermatitis (AD) and sensitisation against common food allergens in infants at high risk of atopic disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee at the Samsung Medical Center gave approval on the 14th March 2005 (ref: 2005-03-033)

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atopic eczema

Interventions
The selected participants were assigned to treatment groups by computerised block-randomisation and received either probiotics or placebo. Mothers in the probiotics group took a mixture of Bifidobacterium bifidum BGN4 (1.6 x 10^9 colony forming units [CFU]), Bifidobacterium lactis AD011 (1.6 x 10^9 CFU) and Lactobacillus acidophilus AD031 (1.6 x 10^9 CFU) in 0.72 g of maltodextrin and 0.8 g of alpha-corn (Bifido Inc., Hongchungun, Korea) once daily from 4 weeks before delivery to 3 months after delivery. Infants were fed the same powder dissolved in breast milk, infant formula, or sterile water from 4 to 6 months of age.

Mothers and infants in the placebo group took maltodextrin and alpha-corn without probiotic bacteria. All mothers were requested to breastfeed their infants for at least 3 months after birth. Thereafter, they were permitted to feed their infants with cow's milk formula.

Lactating mothers and infants were prevented from eating peanuts and eggs, as well as yogurt and other probiotic functional foods, during the course of the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Probiotics (Bifidobacterium bifidum, Bifidobacterium lactis, Lactobacillus acidophilus)

Primary outcome measure
1. Rate of caesarean delivery, collected at 3 months of infant's age
2. Total duration of the breastfeeding, collected at 3, 6, and 12 months of infant's age
3. Infections, collected at 3, 6, and 12 months of infant's age
4. Antibiotic use, collected at 3, 6, and 12 months of infant's age
5. Hospitalisation during infancy, collected at 3, 6, and 12 months of infant's age
6. Prevalence of respiratory infection and acute gastroenteritis, collected at 3, 6, and 12 months of infant's age
7. Frequency of fever above 38.5°C, collected at 3, 6, and 12 months of infant's age
8. Serious adverse events related to the administration of probiotics, collected at 3, 6, and 12 months of infant's age

Secondary outcome measures
1. Effects of probiotics on development of atopic dermatitis, collected at 3, 6, and 12 months of infant's age
2. Severity of AD, assessed by the Six Area Six Sign Atopic Dermatitis (SASSAD) scoring system, collected at 3, 6, and 12 months of infant's age
3. IgE sensitisation, measured at 1 year of infants' age

Overall study start date
01/01/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
Pregnant adult women with a family history of atopic diseases. A positive family history was defined as the presence of at least one first-degree family member having AD, asthma, or allergic rhinitis. The AD of members of the participants' families was confirmed by a physician at enrolment. Those who had been diagnosed as having asthma or allergic rhinitis were selected only when they showed house dust mite-specific immunoglobulin E (IgE) over 1.0 kU/l by cap-system fluorescent enzyme immunoassay (CAP-FEIA) (Pharmacia, Uppsala, Sweden).

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
110

Total final enrolment
112

Key exclusion criteria
1. Babies with a congenital disorder
2. Premature babies

Date of first enrolment
01/01/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Korea, South

Study participating centre
San 56-1, Shinlimdong
Seoul
Korea, South
152-742

Sponsor information

Organisation
Ministry for Health, Welfare and Family Affairs (South Korea)

Sponsor details
75, Yulgong-ro
Jongno-gu
Seoul

Korea, South
110-793
-
kchangu@khidi.or.kr

Sponsor type
Government

Website
http://english.mw.go.kr/front_eng/main.jsp

ROR
https://ror.org/00vxgjw72

Funder(s)

Funder type
Government

Funder Name
Ministry for Health, Welfare and Family Affairs (South Korea) (grant ref: A060546 and A080664)

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	01/03/2010	10/07/2019	Yes	No