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Probiotics in the prevention of atopy in infants and children

Submission date	Recruitment status	[_] Prospectively registered
27/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2025	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Probiotics in the prevention of atopy in infants and children (PROBAT)

Acronym
PROBAT

Study objectives
Administration of probiotic organisms will reduce the incidence of atopy in infants and children and favourably influence key immune parameters associated with atopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved February 2004, South West Wales Research Ethics Committee (no address; no telephone number; no email address), ref: 2004024

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Atopy in infants and children

Interventions
Active intervention: probiotic supplement consisting of a combination of 4 strains of live bacteria (Lactobacillus salivarius LS33 6.25 x 10^9 cfu [Colony Forming Units], Lactobacillus paracasei CUL08 1.25 x 10^9 cfu, Bifidobacterium infantis Bi07 1.25 x 10^9 cfu and Bifidobacterium bifidum CUL20 1.25 x 10^9 cfu), as 100 mg freeze dried powder.

Placebo: maltodextrin 100 mg.

Mother takes the trial preparation daily with food, from 36 weeks gestation until delivery. After delivery, the preparation is administered to the baby daily from birth to age six months, either with feeds or directly into the mouth.

Intervention Type
Supplement

Primary outcome(s)
1. The presence of eczema during infancy (assessed by the SCORAD system)
2. The presence of asthma in children in the first five years
3. Changes in key immunological parameters associated with atopy

Key secondary outcome(s))
1. Compliance with/adherence to trial intervention
2. Adverse events

Completion date
31/07/2021

Eligibility

Key inclusion criteria
600 women and their newborn infants recruited from the antenatal department of a maternity unit of a district general hospital, with informed written consent. Infants have a first degree relative with an atopic disorder.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
454

Key exclusion criteria
1. Mother aged less than 16 years
2. Multiple pregnancy
3. Gestation at delivery less than 36 weeks
4. Parents unable or unwilling to give informed consent
5. Any adverse medical condition affecting the pregnancy or its likely outcome (e.g. known abnormality in foetus)
6. Member of sibship or household already recruited to the study

Date of first enrolment
01/05/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Clinical School
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
University of Wales, Swansea (UK)

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Government

Funder Name
Knowledge exploitation fund, Collaborative Industrial Research Project number: HE 09 COL 1002, Welsh Assembly Government (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to terms and consideration of ethical and governance approvals. Data will be made available upon reasonable request to the project team. Detailed data are available in the supplementary material of https://www.ncbi.nlm.nih.gov/pubmed/29769554. At the time of writing, the researchers hold data for the 2- and 5-year follow up.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2010		Yes	No

Results article	5-year extension results	01/11/2014		Yes	No
Results article		16/05/2018	24/10/2019	Yes	No
Results article	Exploratory follow-up	09/07/2013	28/06/2021	Yes	No
Abstract results				No	No
Other publications		25/04/2025	28/05/2025	Yes	No