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Probiotics in the prevention of atopy in infants and children

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

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 measure
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

Secondary outcome measures
1. Compliance with/adherence to trial intervention
2. Adverse events

Overall study start date
01/05/2005

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

Age group
Adult

Sex
Female

Target number of participants
600

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)

Sponsor details
Singleton Park
Swansea
Wales
United Kingdom
SA2 8PP

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Abstract results				No	No
Results article		01/03/2010		Yes	No
Results article		01/11/2014		Yes	No
Results article	5-year extension results	16/05/2018	24/10/2019	Yes	No
Results article		09/07/2013	28/06/2021	Yes	No
Other publications	Exploratory follow-up	25/04/2025	28/05/2025	Yes	No