

Probiotics in the prevention of atopy in infants and children

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gareth Morgan

Contact details
Clinical School
University of Wales
Singleton Park
Swansea
United Kingdom
SA2 8PP
+44 (0)1792 513390
gareth.morgan@swansea.ac.uk

Additional identifiers

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

Primary study design

Interventional

Study design

Randomized controlled trial

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 6.25×10^9 cfu [Colony Forming Units], Lactobacillus paracasei CUL08 1.25×10^9 cfu, Bifidobacterium infantis Bi07 1.25×10^9 cfu and Bifidobacterium bifidum CUL20 1.25×10^9 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	5-year extension results	01/03/2010		Yes	No
Results article		01/11/2014		Yes	No
Results article		16/05/2018	24/10/2019	Yes	No
Results article		09/07/2013	28/06/2021	Yes	No
Abstract results				No	No

[Other publications](#)

Exploratory follow-up

25/04/2025

28/05/2025

Yes

No