Probiotics in the prevention of atopy in infants and children

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/04/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/06/2005	Completed	[X] Results		
Last Edited 28/05/2025	Condition category Signs and Symptoms	[] Individual participant data		
Z0/U3/ZUZ3	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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