

# Probiotics in Atopic Dermatitis in Infancy

<b>Submission date</b> 27/10/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/05/2014	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Clare Murray

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01.19.NRC

## Study information

Scientific Title

**Acronym**

PADI

**Study objectives**

Gastrointestinal flora abnormal in infants with atopic dermatitis (defective Th1/2 regulation).  
The abnormality can be corrected by probiotic supplementation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Yes - 24/10/2001 - ref: 01/320

**Study design**

Prospective, randomised, placebo-controlled, double blind, single centre, parallel design

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Atopic dermatitis

**Interventions**

Randomised placebo controlled trial to study the effect of supplementing infants diet with either Bifidobacterium lactis or Lactobacillus paracasei.

Comparisons:

1. Bifidobacterium versus Lactobacillus
2. Bifidobacterium versus Placebo
3. Lactobacillus versus Placebo

All randomised infants on dairy free diet. Open observational groups (exclusively breastfed, standard formula fed = not for formal hypothesis testing).

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Bifidobacterium lactis, Lactobacillus paracasei

**Primary outcome measure**

The primary outcome measure is the change in SCORAD index from the beginning of study treatment to the end of the treatment phase, week 12.

**Secondary outcome measures**

1. The administration of probiotics to infants resulting in colonisation of the gastrointestinal tract will be investigated by Polymerase Chain Reaction (PCR) examination of stool specimens before, during and after administration
2. Blood will be taken at randomisation (week 0) and at week 12 for measurement of total and specific Immunoglobulin E (IgE) and Eosinophil Cationic Protein (ECP)
3. Stool Tumour Necrotising Factor-alpha (TNFα) will be measured at week 0, at week 12 and at age 1 year
4. Subjects will be reviewed at age 1 year, when SCORAD scores and information regarding history of wheeze will be sought
5. Infants will be weighed and measured at each visit, and plotted on a growth chart (UK cross-sectional reference data: 1996/1, child growth foundation)
6. All adverse events (minor and serious)

**Overall study start date**

01/03/2002

**Completion date**

30/05/2004

## **Eligibility**

**Key inclusion criteria**

1. Age 3 - 6 months
2. Be within the 2nd and 98th centiles for weight (ref: UK cross-sectional data 1996:1)
3. Have a physician diagnosis of atopic dermatitis
4. SCORing Atopic Dermatitis (SCORAD) score greater than 10 at visit 1

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

3 Months

**Upper age limit**

6 Months

**Sex**

Both

**Target number of participants**

250

**Key exclusion criteria**

1. Preterm, born before 34 weeks gestation
2. Congenital abnormality or suffering from a chronic disease such as: cystic fibrosis, immune deficiency or malabsorption syndrome
3. Currently taking antibiotics
4. Already using a soya or hydrolysed formula

**Date of first enrolment**

01/03/2002

**Date of final enrolment**

30/05/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

NWLRC

Manchester

United Kingdom

M23 9LT

## **Sponsor information**

**Organisation**

Wythenshawe Hospital (UK)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05vpsdj37>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Nestec Ltd (UK) (ref: 01.19.NRC)

**Funder Name**

North West Lung Research Centre Endowment Fund (UK) - c/o Professor Woodcock

## 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?
<a href="#">Results article</a>	results	01/01/2012		Yes	No