Probiotics in Atopic Dermatitis in Infancy

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/10/2005		Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
28/11/2005		[X] Results		
Last Edited		[] Individual participant data		
01/05/2014	Skin and Connective Tissue Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Clare Murray

Contact details

NWLRC Wythenshawe Hospital Southmoor Road Manchester United Kingdom M23 9LT +44 (0)161 291 4199

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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 (TNF α) 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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 months

Upper age limit

6 months

Sex

All

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

Locations

Countries of recruitment

United Kingdom

England

Study participating centre NWLRC

Manchester United Kingdom M23 9LT

Sponsor information

Organisation

Wythenshawe Hospital (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No