ISRCTN41490500 https://doi.org/10.1186/ISRCTN41490500

Probiotics in Atopic Dermatitis in Infancy

Submission date	Recruitment status	[_] Prospectively registered
27/10/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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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
Andrew Maines
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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?
Results article	results	01/01/2012		Yes	No