ISRCTN52995544 https://doi.org/10.1186/ISRCTN52995544

Primary prevention of atopic disease by perinatal administration of probiotics

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
18/11/2008

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary
Not provided at time of registration

Study website
http://www.kinderallergologie.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR323

Study information

Scientific Title

Acronym
PANDA

Study hypothesis
Administration of probiotics to pregnant women from an atopic family and subsequently to their high-risk newborns results in prevention of the incidence of or in a decrease of the severity of atopic disease during infancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, double-blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Condition
Allergy, atopic disease, pregnancy

Interventions
A combination of probiotics (Lactococcus lactis, Bifidobacterium bifidum, Bifidobacterium infantum), each 1000 million daily, added to the formula used.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Probiotics (Lactococcus lactis, Bifidobacterium bifidum, Bifidobacterium infantum)

Primary outcome measure
Incidence and severity of atopic disease at the age of 2 years.

Secondary outcome measures
1. SCORAD
2. Lung function
3. Serum IgE (total and specific)
4. Cytokines produced by peripheral blood derived mononuclear cells
5. Bacterial content of stools during the first weeks of life

Overall study start date
01/01/2004

Overall study end date
01/01/2009

Eligibility

Participant inclusion criteria
Pregnant mothers were included if either they themselves or their husband plus a sibling suffered from present or past atopic disease.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Participant exclusion criteria
1. Maternal use of immunomodulatory drugs during pregnancy
2. The use of probiotics

Recruitment start date
01/01/2004

Recruitment end date
01/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wilhelmina Children's Hospital (WKZ) (The Netherlands) - research fund

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