

Primary prevention of atopic disease by perinatal administration of probiotics

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/11/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.kinderallergologie.nl>

Contact information

Type(s)
Scientific

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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 objectives

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

Health condition(s) or problem(s) studied

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

Completion date

01/01/2009

Eligibility

Key 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

Key exclusion criteria

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

Date of first enrolment

01/01/2004

Date of final enrolment

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