

Primary prevention of atopic disease by perinatal administration of probiotics

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M O Hoekstra

Contact details
University Medical Centre Utrecht
Wilhelmina Children's Hospital
P.O. Box 85090
Utrecht
Netherlands
3508 AB
+31 (0)30 250 4001
m.o.hoekstra@umcutrecht.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes