Primairy prevention of atopic disease by perinatal administration of probiotics.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26444

Source
Nationaal Trial Register

Brief title
PANDA

Health condition

A randomised double-blind intervention study in pregnant mothers from atopic families and in their newborns.

Sponsors and support

Primary sponsor: Wilhelmina Children's Hospital, PO box 85090, 3508 AB Utrecht, The Netherlands.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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.

Study description

Background summary

Inclusion of pregnant mothers from atopic families has ended. Around January first 2006 all children are born. Results on cord blood analysis are expected in spring of 2006. Clinicial data at the age of 3 months are expected just before the summer of 2006.

Study objective

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.

Intervention

A combination of probiotics (Lact.Lactis, B.Bifidum, B.Infantum), each 1000 milion daily, added to the the formula used.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2004
Enrollment:	120

Type:	Anticipated

Ethics review

Positive opinion Date:	09-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL285
NTR-old	NTR323
Other	: N/A
ISRCTN	ISRCTN52995544

Study results

Summary results
N/A