

Asthma, a disease due to a lack of bacterial infections in childhood.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20850

Source

Nationaal Trial Register

Brief title

INDIAAN

Health condition

A randomised single-blinded intervention study in high-risk newborns vaccinated at the age of 6 weeks with BCG or placebo.

Sponsors and support

Primary sponsor: Dutch Organisation for Scientific Research (NWO) and Netherlands Asthma Foundation (NWO-NAF 3.2.93.96.2)

Source(s) of monetary or material Support: Dutch Organisation for Scientific Research (NWO) and Netherlands Asthma Foundation (NWO-NAF 3.2.93.96.2)

Intervention

Outcome measures

Primary outcome

Incidence and severity of atopic disease at the age of 4 years.

Secondary outcome

1. SCORAD;
2. Lung function;
3. Cytokine production;
4. NRAMP-polymorphisms.

Study description

Background summary

No effect of BCG vaccination in 6 weeks old high-risk infants on clinical or immunological parameters was observed at the age of 18 months. However, in a post-hoc analysis a beneficial effects was observed in children from non-allergic mothers (i.e. fathers + sibling allergic).

Study objective

The degree of TH1-skewing by mycobacteria is controlled by NRAMP1 gene polymorphisms and related to the degree of inhibition of TH2-mediated disease.

Intervention

BCG vaccination or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

High-risk newborns. High-risk was defined as either a mother or a father plus a sibling with present or past atopic disease.

Exclusion criteria

1. Maternal infection in the last week of pregnancy;
2. The use of immunomodulatory drugs or antibiotics during pregnancy (mother);
3. The use of antibiotics prenatally (mother and newborn);
4. Prematurity;
5. Signs of intra-uterine infection;
6. Premature rupture of membranes;
7. Presence of congenital disorders of the airways;
8. Sever other congenital disorders;
9. Need for mechanical ventilation;
10. Prolonged administration of extra oxygen;
11. Need for intensive care treatment.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1999
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion	
Date:	09-11-2005
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	NL311
NTR-old	NTR349
Other	: NWO-NAF 3.2.93.96.2
ISRCTN	ISRCTN54378178

Study results

Summary results

N/A