Evaluation of the effect of early BCG-vaccination on development of asthma and allergic rhinitis during childhood - follow-up study at age 7 years.

Published: 20-05-2008
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To establish the effect of BCG vaccination in 6 weeks old high-risk infants on the prevalence of asthma and allergic rhinitis at the age of 7 years.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON36994

Source
ToetsingOnline

Brief title
Follow-up study on BCG vaccination and atopy

Condition

- Allergic conditions

Synonym
asthma, hayfever

Research involving
Human

Sponsors and support

Primary sponsor: Kinderlongziekten
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: allergic rhinitis, asthma, atopy, BCG

Outcome measures

Primary outcome

Asthma, defined by periodic wheezing and dyspnoea, combined with a 9%

reversibility in FEV1 and/or exhaled NO above 20 ppb.

Allergic rhinitis. defined by periodic or perennial sneezing, runny or blocked

nose when not having a cold or the flu.

Secondary outcome

Nitric oxide measurements in nasal air, specific IgE to allergens and

immunologic parameters in serum.

Study description

Background summary

The increase in prevalence of allergic diseases in countries with a so-called Western lifestyle may be due to a decreased exposure to infectious agents in early life.

Study objective

To establish the effect of BCG vaccination in 6 weeks old high-risk infants on the prevalence of asthma and allergic rhinitis at the age of 7 years.

Study design

Prospective, single blind, randomised trial.

Study burden and risks

Parents and child are asked to fill in a questionnaire, and pay one visit to the out patient department for physical examination, blood sampling and

pulmonary function testing with measurement of exhaled nitric oxide. The risks of these procedures are negligible and the burden minimal. It should be carried out specifically in these children, since they have been included in the former study and received placebo or BCG vaccination.
A minimal risk is carried in the discontinuation of the beta-mimetics for a short period of maximally 48 hours, and of nasal corticosteroids for 6 weeks in advance of the lung function testing and nasal NO measurements. Participants might observe an increase in wheezing in the first case, in which case the advise is to restart the beta-mimetics. The same applies to an exacerbation of allergic rhinitis, in which case restarting of corticosteroids is adviced or alternative medication. These risks will be deliberated with the treating physician, whose advice will be followed by the investigator.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

participation in study with code WOK 98-24, dd 01-02-1999

Exclusion criteria

no participation in earlier study with code WOK 98-24

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2008
Enrollment:	116
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-06-2011
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL19075.041.07