

Asthma: a disease due to a lack of bacterial infections in childhood

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| 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 15/07/2021 | Condition category Respiratory | <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
NCT00200928

Secondary identifying numbers

NWO-NAF 3.2.93.96.2

Study information

Scientific Title

Asthma: a disease due to a lack of bacterial infections in childhood

Acronym

INDIAAN

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, single blind, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Atopic disease, asthma

Interventions

BCG vaccination or placebo.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

1. SCORing Atopic Dermatitis (SCORAD)
2. Lung function
3. Cytokine production
4. Natural Resistance Associated Macrophage Protein (NRAMP) polymorphisms

Overall study start date

01/01/1999

Completion date

01/07/2005

Eligibility**Key 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.

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

120

Key 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

Date of first enrolment

01/01/1999

Date of final enrolment

01/07/2005

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

Charity

Funder Name

The Netherlands Organization for Scientific Research (NWO) (The Netherlands)

Funder Name

Netherlands Asthma Foundation (The Netherlands)

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