

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

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 15/07/2021	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00200928

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, single blind, placebo controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atopic disease, asthma

Interventions

BCG vaccination or placebo.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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