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The relationship between the microbes in the lower respiratory tract and allergic respiratory diseases in children

Submission date
30/09/2020

Registration date
06/10/2020

Last Edited
07/01/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims
With the development of DNA sequencing technologies, it has been found that there are microbes similar to those in the upper respiratory tract (the nose and nasal cavity, the pharynx, and the larynx) present in the healthy human lower respiratory tract (LRT), including the lungs and bronchi. The aim of this study is to analyse the LRT microbiome and evaluate the relationship between this microbiome and allergic respiratory diseases in children.

Who can participate?
Children who visit the respiratory department and undergo bronchoscopy (a procedure where a tube is inserted through the nose or mouth, down the throat and into the windpipe, bronchi and bronchioles of the lungs)

What does the study involve?
Total IgE (antibody) levels are detected using a special protein analyser. The peripheral blood cell count is measured using an automatic blood analyser. DNA is extracted from samples of fluid taken during bronchoscopy and the microbiome is sequenced and analysed.

What are the possible benefits and risks of participating?
There are no benefits and risks of participating.

Where is the study run from?
The affiliated hospital of the Capital Institute of Pediatrics (China)

When is the study starting and how long is it expected to run for?
January 2018 to May 2020

Who is funding the study?
Beijing Medical Research Institute (China)

Who is the main contact?
Jinghua Cui
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
704209958

Study information

Scientific Title
The relationship between the lower respiratory tract microbiome and allergic respiratory tract diseases in children

Study objectives
A decrease in microbial diversity and change in composition could lead to an increase in allergic symptoms. The colonised microbiota of the lower respiratory tract (LRT) in children, especially that of Bacteriodetes and Streptococcus, show a certain correlation with early respiratory allergic diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/06/2019, the medical ethics committee of the Capital Institute of Pediatrics (Beijing, China. +86 (0)8569 5535; shouerkyb@sina.com), ref: SHERLLM2019006

Study design
Single-centre cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Allergic respiratory tract diseases in children

Interventions
Nucleic acid is extracted from samples of bronchoalveolar lavage fluid (BALF) of children taken during bronchoscopy treatment and the 16S rDNA gene is sequenced and analysed.

Intervention Type
Other

Primary outcome measure
The microbiome in BAFL measured using 16S rDNA sequenced on a MiSeq instrument (Illumina, Inc.) using a Miseq v2 reagent kit (Illumina, Inc.) at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2018

Completion date
01/05/2020

Eligibility

Key inclusion criteria
Children who visit the respiratory department and undergo bronchoscopy

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
68

Total final enrolment
68

Key exclusion criteria
1. Diagnosis of pneumonia with specific pathogen infection such as fungus, virus, or mycoplasma
2. History of mechanical ventilation

Date of first enrolment
01/01/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
China

Study participating centre
The affiliated hospital of the Capital Institute of Pediatrics
Beijing
China
10020

Sponsor information

Organisation
Capital Institute of Pediatrics

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Sponsor type
Research organisation

Website
http://www.shouer.com.cn/en/web/detail.aspx?menuID=515&contentID=3536

ROR
https://ror.org/00zw6et16

Funder(s)

Funder type
Research organisation

Funder Name
Beijing Medical Research Institute (BMR2019-11)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and sharing data on the National Genomics Data Center of the China National Center for Bioinformation (CNCB-NGDC).

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Jinghua Cui (cuijinghua7910@ hotmail.com). After the paper and the data are published, if consent is obtained from the author, the data can be shared with all who are interested in this study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2021	07/01/2022	Yes	No