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Effects of gut microbiome and environment on the development of eczema in Chinese infants

Submission date	Recruitment status
20/02/2020	No longer recruiting
Registration date	**Overall study status**
29/02/2020	Completed
Last Edited	**Condition category**
17/06/2021	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Eczema is a relapsing and persistent inflammatory skin disease affecting about one-fifth of children worldwide. As in other developed countries, the prevalence of this chronic disease in Hong Kong is approximately 30%. Moreover, the number of local cases reported has been on a rising trend since 1995. Eczema frequently starts in early infancy. A total of 45% of all cases begin within the first six months of life, 60% during the first year and 85% before the age of five. The aims of this study are to characterize the changes of gut microbial profile in early childhood and to examine the association between microbiome diversity, environmental factors and the development of eczema in early childhood.

Who can participate?
Full-term newborns within 10 days from birth with Chinese ethnicity and residing in Hong Kong

What does the study involve?
Parents are asked to provide demographic data, their infant's birth data and allergy condition by questionnaires. Stool specimens from the newborns are collected for gut microbiome diversity testing. For a better understanding of the prevalence and severity of eczema, the infants are followed for 2 years, with four follow-up measurement points to assess maternal stress, gut microbiota, diet, environment and allergy condition of the infants at the ages of 10 days, 4 months, 1 year and 2 years.

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

Where is the study run from?
The Chinese University of Hong Kong (Hong Kong)

When is the study starting and how long is it expected to run for?
September 2016 to December 2020

Who is funding the study?
The Chinese University of Hong Kong (Hong Kong)

Who is the main contact?
Prof. Carmen Chan
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Early-life gut microbiome and environmental factors in the development of eczema in Chinese children

Study objectives
1. Early-life environmental and lifestyle risk factors are associated with the development of eczema
2. There is longitudinal association of gut microbiome diversity in the development of eczema in early childhood
3. Microbiome diversity mediates the relationships between development of eczema and environmental and lifestyle factors identified

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/08/2016, The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; Tel: +852 (0)26323935; Email: crec@cuhk.edu.hk), Approval #2016.321

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Eczema

Interventions
This will be a prospective birth cohort study of 1,250 Chinese newborns in which parents will be asked to provide demographic data, their infant birth data and allergy condition by questionnaires. Stool specimens from the newborns will be collected for gut microbiome diversity testing. For a better understanding of the prevalence and severity of eczema, the cohort will be followed for two years, with three follow-up measurement points to assess the diet, environment, allergy condition and gut microbiome changes of the infants at the ages of four months, one year and two years. Parental stress will also be assessed at three timepoints. Because of the large sample size and two-year follow up, it is expected that the study will take 36 months to complete.

Intervention Type
Other

Primary outcome(s)
Gut microbiome diversity profile analysed by 16S sequencing of DNA extracted from the stool at enrolment, 4 months, 1 year and 2 years

Key secondary outcome(s))
Measured at enrolment, 4 months, 1 year and 2 years:
1. Infant’s allergy condition assessed by the modified parent proxy version of the Comprehensive Early Childhood Allergy Questionnaire
2. The subjects’ dietary factors assessed by a parent proxy dietary practice questionnaire, adopted from the Chinese version of the eating-habit module of the Behavioural Risk Factor Surveillance System
3. Parents’ level of stress assessed by ten-item Perceived Stress Scale

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Full-term infants
2. Chinese ethnicity
3. Resident in Hong Kong

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
215

Key exclusion criteria
1. Infants with GI disorders after birth
2. Admitted to neonatal ICU
3. Mothers have fever or an infection or are currently taking antibiotics

Date of first enrolment
29/11/2016

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Nethersole School of Nursing, The Chinese University of Hong Kong
Esther Lee Building
The Chinese University of Hong Kong
Hong Kong
Hong Kong
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Study participating centre
Department of Paediatrics, The Chinese University of Hong Kong
Prince of Wales Hospital, Shatin

Hong Kong
Hong Kong
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Sponsor information

Organisation
Chinese University of Hong Kong

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong

Alternative Name(s)
The Chinese University of Hong Kong, , , Hēunggóng Jūngmàhn Daaihhohk, CUHK,

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	20/10/2020	15/06/2021	Yes	No
Results article		01/11/2018	17/06/2021	Yes	No
Interim results article		19/01/2021	15/06/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes