

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

Submission date 20/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/02/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/06/2021	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Longitudinal study

Study setting(s)

Home

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2016

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

Age group

Neonate

Sex

Both

Target number of participants

1250

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

Sponsor details

The Nethersole School of Nursing

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nursing@cuhk.edu.hk

Sponsor type

University/education

Website

<http://www.nur.cuhk.edu.hk/home-page/>

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 , CUHK

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Hong Kong

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journals at 6-12 months after the data collection was ended.

Intention to publish date

30/06/2021

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?
Interim results article		19/01/2021	15/06/2021	Yes	No
Results article	pilot study results	20/10/2020	15/06/2021	Yes	No
Results article		01/11/2018	17/06/2021	Yes	No