The Amsterdam Infant Microbiome Study

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Objective: We propose the Amsterdam Infant Microbiome Study (AIMS). The general objective of AIMS is to establish a research infrastructure that allows for explorative research on the development of the microbiome in relation to healthy growth and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52873

Source
ToetsingOnline

Brief title
AIMS

Condition

- Other condition

Synonym
caries, Obesity, severe overweight

Health condition

Overgewicht/obestitas en mondgezondheid

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Body weight, Infant, Microbiome, Oral health

Outcome measures

Primary outcome

Main study parameters/endpoints: Primary endpoints will be growth trajectories and oral health. Growth trajectories will be measured using data from the youth health care visits to calculate BMI z score. In addition, fat percentage will be measured using the BodPod® when children reach the age of 3 years. Oral health (i.e. dental caries) will be measured during a clinical oral examination in both infants and their mothers. The main focus will be on the influence of the microbiome on both growth trajectories and oral health. In addition, factors such as health status, lifestyle and nutrition will be measured by questionnaires at 8 time points.

Secondary outcome

See above

Study description

Background summary

Rationale: Childhood overweight and obesity have become an epidemic problem worldwide. Also in Amsterdam, 19% of the children are currently overweight or obese. Another public health problem is dental caries. in The Netherlands, nowadays 41% of the five-year-old children suffer from caries. Increasing evidence points to the microbiome as potential explanatory these chronic diseases. The human microbiome develops in the first three years of life and is influenced by a range of environmental factors such as mode of birth, type of feeding and antibiotics use. A disturbance of the microbiome may affect the onset of weight gain and caries. However, studies in early childhood that examine the full development of the microbiome in relation to weight gain and

caries are lacking.

Study objective

Objective: We propose the Amsterdam Infant Microbiome Study (AIMS). The general objective of AIMS is to establish a research infrastructure that allows for explorative research on the development of the microbiome in relation to healthy growth and development. There will be a special focus on growth trajectories and oral health, and special attention for the role of nutrition and other lifestyle factors in children aged 0 - 3 years old from the ethnically diverse population of Amsterdam.

Study design

Study design: AIMS is a multi-ethnic, prospective birth cohort study in 1,000 children, their mothers and other family members (i.e. partner and one sibling). Mothers will be recruited mid-pregnancy and the infants will be followed from birth until the age of 3 years. We will collect bio samples from the children at 11 time points from birth until the age of 3 years and from their mothers at 3 time points (during pregnancy, birth, and when the infant is 6 months old). Also, we will collect bio samples from the partner and sibling during pregnancy of the mother and when the infant is 6 months old. We will collect faecal-, vaginal-, saliva-,tooth plaque,- skin-, and breast milk samples from the mother, and faecal-, tooth plaque-, saliva- samples from the infant, and partner/sibling. Hence we will focus mainly on the gut and oral microbiota.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The study described in this protocol will be an observational study. The data will be collected by means of questionnaires, and anthropometry as part of the regular youth health care. We will collect bio samples that are all non-invasive. In addition, we will collect clinical data using the BodPod® when children are three years old , and perform clinical oral examinations by professionals in both mother and infant when the children are 14 and 36 months old. We expect no adverse or serious adverse events of these non-invasive data collection methods. Where possible we want to limit the participant burden as much as possible by for example using self-collection kits. There is no group relatedness attached to this study since all ethnicities will be included.

This study will allow us to really disentangle under which lifestyle, nutritional and environmental factors the changes in the microbiome of the infant occur, to study when they occur, and to study how these changes are related with growth trajectories and oral heath in the different ethnic groups.

Results of this study may open up new avenues for the prevention of childhood overweight and obesity and oral health problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

In the 26th week of pregnancy
Living in Amsterdam Noord, Nieuw-West or Oost
Medically fit to participate according to the judgment of their midwife

Exclusion criteria

Serious perinatale/ neonatale/ maternale complications
Serious congenital abnormalities
Intention to move out of city districts Amsterdam Noord, Nieuw-West or Oost
Mothers under the age of 18

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2019
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	08-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64399.018.17