LLNEXT, prenatal and early life data in Lifelines

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To investigate the effect of early life or pre-conceptional transgenerational events on healthy ageing and chronic disease in (early) childhood. Eventually this may lead to determine parameters for (early) life health and its impact on health. We...

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

Summary

ID

NL-OMON50411

Source
ToetsingOnline

Brief title
LLNEXT

Condition

- Other condition

Synonym
Early life development

Health condition

gezondheid in het algemeen

Research involving
Human

Sponsors and support

Primary sponsor: Genetica
Source(s) of monetary or material Support: Fonds erfelijke stofwisselingsstoornissen UMCG

Intervention

Keyword: Early life development, Healthy ageing, Microbiome, Prospective birth cohort

Outcome measures

Primary outcome

Collection of biomaterials in 1500 - maximally 2000 subjects in the LLNEXT

cohort to correlate serological, metabolomic, microbiomic, genomic,

transcriptomic, epigenetic, medical, social and environmental factors to early

life health.

Secondary outcome

nvt

Study description

Background summary

To study intrinsic and external factors for health development in early childhood cohort studies including immune status and microbiome, longitudinal data in prenatal and early life of both the pregnant women and the newborns are needed. We aim to build a birth cohort within Lifelines and include at least 1500 pregnant LL participants. This will enable us using -omics techniques to correlate genomic, epigenetic, serological, metabolomic, microbiomic, medical, social and environmental factors to early life health.

Study objective

To investigate the effect of early life or pre-conceptional transgenerational events on healthy ageing and chronic disease in (early) childhood. Eventually this may lead to determine parameters for (early) life health and its impact on health. We will first relate microbiome (using metagenomic

sequencing) to early life development and early life events.

Study design

This is a non-therapeutic observational study with an expected duration of 3 years.

Study burden and risks

The study involves venepuncture, collection of nasal, mouth and vaginal smears, placenta, stool, breast milk, exhaled breath and urine samples longitudinally in mother and child. We will assess lung function in the new-borns. Data on medical, environmental and social data acquired from questionnaires. In total we will collect 2x30 ml venous blood from the mother, 1x max 10 ml of cord blood, 3x max 1 ml capillary blood and 1x max 1 ml venous blood from the child. In total a maximum of 19 bio samples from the child and 24 from the mother will be taken. A maximum of 21 questionnaires about the child*s health and 26 about the mothers/caregivers life style will be filled out. The sample collection will be performed as much as possible by the participant herself at home at 9 timepoints. Samples drawn by healthcare professionals will be taken at 7 timepoints during home visits or regular contact moments with health care professionals. There are no adverse events anticipated to be associated with these procedures.

Contacts

Public
Selecteer

A. Deusinglaan 1
Groningen 9713 AV
NL
Scientific
Selecteer

A. Deusinglaan 1
Groningen 9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant LifeLines participants

Exclusion criteria

Presence of one of the exclusion criteria will exclude a pregnant LL participant from participation in this study:
- no informed consent obtained for this study
- not being able to fill in the questionnaires
- not being able to donate bio samples

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2016
Enrollment:	1500

Type:	Actual

Ethics review

Approved WMO Date:	22-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-02-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-09-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL56068.042.15