Hunger Winter Generations Study (The HWG Study)

Published: 10-02-2015
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The objective of this study is to investigate whether the differences in DNA methylation between individuals who were exposed in utero to the Dutch Hungerwinter (F1) and their non-exposed, same-sex siblings (F1) - as identified in epigenome-wide...

Ethical review	Approved WMO
Status	Suspended
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON41296

Source
ToetsingOnline

Brief title
HWG study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Malnutrition during pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: DNA methylation, Hungerwinter, Intergenerational epigenetics

Outcome measures

Primary outcome

To investigate whether the differences in DNA methylation between individuals who were exposed in utero to the Dutch Hungerwinter and their non-exposed, siblings as identified in epigenome-wide studies are transmitted to a second generation.

Secondary outcome

Secondary endpoint of this study is the measurement of genetic variation. DNA methylation differences within and between generations may be driven or confounded by genetic variation.

Study description

Background summary

There is an increasing concern that adverse circumstances during gestation not only influence health of the prenatally exposed individual but will also of their offspring. Such intergenerational effects may explain the current epidemic in non-commutable diseases (NCDs) including obesity and type 2 diabetes. Although still controversial, epigenetic mechanisms are frequently invoked as an explanation. Few human studies are suitable to address this hypothesis in humans. Studies on historical famines, in particular the Dutch Hunger Winter, may be among the best-suited possibilities.

Study objective

The objective of this study is to investigate whether the differences in DNA methylation between individuals who were exposed in utero to the Dutch Hungerwinter (F1) and their non-exposed, same-sex siblings (F1) - as identified in epigenome-wide studies - are transmitted to a second generation

(F2).

Study design

A family based follow-up study with in utero (F1) and indirect (F2) to the Dutch Hungerwinter exposed subjects compared with non-exposed siblings (F1, F2).

Study burden and risks

The risks to participate in this study are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Preferably families will be included where the exposed F1 (F1e) and the non-exposed sibling (F1c) together with two of their offspring (F2e, F2c), i.e. four subjects in one family (F1e, F1c, F2e, F2c) agree to participate. However, incomplete families will be included as well.

Exclusion criteria

We will exclude control individuals if they were born between November 1944 and March 1946 and lived in a town that was known to be affected by the Dutch Famine.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	15-01-2015
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-02-2015
Application type:	First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL47531.058.14