Maternal telomere length as novel biomarker to assess the risk of SB in offspring.

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The primary objective is to study the association between maternal TL and the risk of SB in offspring. The secondary objectives are to investigate the relation between maternal TL and obstetrical (pregnancy course and outcome), environmental risk...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON49698

Source
ToetsingOnline

Brief title
Maternal telomere length and risk of SB in offspring.

Condition

- Neurological disorders congenital
- Spinal cord and nerve root disorders
- Neonatal and perinatal conditions

Synonym
neural tube defect, Spina Bifida

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lifestyle, Maternal telomere length, Oxidative stress and inflammation, Risk of SB in offspring

Outcome measures

Primary outcome

The difference in TL in cases and controls to assess the risk of SB in the

offspring. *

Secondary outcome

Our secondary study parameters are to assess the relation between maternal TL

and obstetrical (pregnancy course and outcome), environmental risk factors

(such as lifestyle, diet, obesity), and biochemical markers of oxidative

stress.

Study description

Background summary

Neural tube defects (NTDs) are severe birth defects involving the central nervous system. NTDs, like spina bifida, are complex disorders caused by genetic and periconceptional maternal environmental factors that can induce excessive oxidative stress and inflammation. Embryogenesis in very early pregnancy is sensitive to excessive oxidative stress, including the development and folding of the neural tube. For that reason, the identification of a stable marker of the periconception oxidative status in women will help to predict the risk of SB in offspring and offers opportunities for prevention.
A number of molecular markers for biological ageing have already been identified, including telomere length (TL). Telomeres are nucleoprotein structures located at the end of chromosomes and the length can be measured as a stable marker. Telomeres protect chromosomes from degradation, but in the absence of a compensatory elongating mechanism, they become shorter with each cell division. TL shortening is associated with exposure to environmental and lifestyle factors that can induce oxidative stress and inflammation. We

hypothesize that preconceptional exposure to environmental risk factors accelerates a woman*s ageing process and thereby the underlying risk of SB in offspring, to be estimated by TL.

Study objective

The primary objective is to study the association between maternal TL and the risk of SB in offspring. The secondary objectives are to investigate the relation between maternal TL and obstetrical (pregnancy course and outcome), environmental risk factors (such as lifestyle, diet, obesity), and biochemical markers of oxidative stress.*

Study design

Retrospective case control study.*

Study burden and risks

Participants are asked to draw one blood sample. This will be combined with a site visit and physical examination including blood pressure, length and weight. Although taking blood is a very safe procedure, it can be uncomfortable and may result in local bruising.

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

Cases
- At least 18 years of age.
- Singleton pregnancy.
- Pregnant or gave birth to a child with SB between January 2005 and January 2021.
- Familiar with the spoken and written Dutch language

Controls
- At least 18 years of age
- Singleton pregnancy
- Pregnant or gave birth to a child without congenital malformations between June 2003 until January 2010
- Familiar with the spoken and written Dutch language

Exclusion criteria

Not applicable.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	28-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL74083.078.20