The context of increased nuchal translucency thickness early in pregnancy

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The objective of the NEK-study is the clinical relevance of increased nuchal translucency in fetuses with a CRL =2.5mm. Expectant parents can receive better counselling for their ongoing pregnancy if the clinical relevance is clear.

Ethical review	Approved WMO
Status	Completed
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55184

Source
ToetsingOnline

Brief title
NEK-study

Condition

- Neonatal and perinatal conditions

Synonym
first trimester, nuchal translucency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: First trimester, Nuchal Translucency, Ultrasound

Outcome measures

Primary outcome

The incidence of chromosomal anomalies detected prenatally and after birth, in fetuses with normalized NT and fetuses with persistent increased NT

Secondary outcome

The incidence of structural anomalies, perinatal loss and composite abnormal outcome (defined as diagnosed chromosomal anomalies, single gene disorders, structural anomalies, perinatal loss or deceased during follow-up period), compared in fetuses with normalized NT and fetuses with persistent increased NT. The proportion of fetuses in which the NT normalizes after 11 weeks of gestation. The incidence of congenital anomalies not detected by NIPT. The incidence of structural anomalies at the 13 weeks scan, 20 weeks scan and after birth.

Pregnancy outcomes such as pregnancy loss before 24 weeks of gestation, intra-uterine death or neonatal death before hospital discharge. In specific we will regard also perinatal outcomes as: number of terminations of pregnancy, stillbirths, mean gestational age at birth, birthweight and APGAR-scores.

Study description

Background summary

In the current guideline the cut-off point of NT-measurement is based on the p99 value of the normal distribution in the population, thus the incidence of

increased NT-measurement is 1%. A recent Dutch study in 1901 fetuses revealed a 21% abnormality rate for fetuses with NT between 95th and 99th percentile and 62% for fetuses with NT>=99th percentile. In this population, the incidence of chromosomal anomalies was 43.2%, increasing with increasing magnitude of the NT-measurement. In contrast, little is known about the meaning of an increased NT at a CRL below 45mm, thus below 11 weeks* pregnancy. Currently, when an increased nuchal translucency is observed before 11 week*s pregnancy, ultrasonographers are advised to repeat the ultrasound examination and NT measurement in the correct timeframe above 11 weeks. In the case the NT normalises, women can opt for prenatal screening such as the combined screening test or a non-invasive prenatal test (NIPT) to test for the most common aneuploidies such as trisomy 21, 18 and 13. Those cases with still an increased NT are referred for further counselling in a fetal medicine unit and will be offered chorionic villus sampling for genetic testing. At present, it is unclear in which percentage of fetuses NT will normalize and how many women are referred to a fetal medicine unit. Moreover, it is unclear if fetuses in which the NT normalises after 11 weeks* pregnancy will develop normally throughout pregnancy and after birth. Therefore, the meaning of an increased early nuchal translucency is unclear and thus far, not much information is available for parents with such a finding

Study objective

The objective of the NEK-study is the clinical relevance of increased nuchal translucency in fetuses with a CRL <45mm and NT measurement of >=2.5mm. Expectant parents can receive better counselling for their ongoing pregnancy if the clinical relevance is clear.

Study design

The design is a prospective multicenter cohort study.

Study burden and risks

There are no known risks to extra ultrasonographic scanning. All patients will receive standard obstetric care. Patients who want to participate will receive an additional scan between 11-13 weeks.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Singleton or twin pregnancies
2. Ultrasound with viable fetus(es) with a CRL between 20-45mm
AND
3. Nuchal translucency measurement >=2.5mm or increased NT with *eyeballing*
4. Written informed consent

Exclusion criteria

1. Maternal age < 16 year
2. Insufficient knowledge of English or Dutch language to comprehend the patient information and consent form
3. Cases of parents with recognized medical history for monogenetic disease or known carriers of a balanced translocation, deletion or duplication

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-05-2021
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2021
Application type:	First submission
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

ID: 23541
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74879.018.21
OMON	NL-OMON23541