NEK-study: The context of increased nuchal translucency thickness early in pregnancy

Published: 25-05-2021
Last updated: 19-03-2025

We hypothesize that the risk of any congenital abnormality in fetuses with an early increased NT that normalizes, will be lower than those with persistent increased NT after 11 weeks of gestation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Foetal complications
Study type	Observational non invasive

Summary

ID

NL-OMON23541

Source
Nationaal Trial Register

Brief title
NEK-studie

Condition

- Foetal complications

Health condition

Chromosomal anomalies. Congenital anomalies.

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Amsterdam UMC

Intervention

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 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.

Study description

Background summary

Rationale: Fetal Nuchal Translucency (NT) thickness is a reliable marker for chromosomal- and structural between 11 and 13+6 weeks. Little is known about its clinical relevance before 11 weeks of gestation. Objective: To estimate the relationship between nuchal translucency thickness early in pregnancy and chromosomal anomalies, structural anomalies, perinatal loss and composite abnormal outcome in fetuses with a NT measurement of ≥2.5mm and a crown rump length (CRL) <45mm. To compare fetuses with a normalized NT and fetuses with persistent increased NT after 11 weeks of gestation. Study design: Prospective cohort study. Study population: Women in the first trimester of pregnancy with a fetus with a NT measurement of ≥2.5mm and a CRL <45mm. Main study parameters: Incidence of chromosomal anomalies.

Study objective

We hypothesize that the risk of any congenital abnormality in fetuses with an early increased NT that normalizes, will be lower than those with persistent increased NT after 11 weeks of gestation.

Study design

Inclusion: 8-11 weeks of gestation Ultrasound and NT-measurement: 11-13 weeks of gestation Follow-up: 4 weeks postpartum

Contacts

Public
Amsterdam UMC, location AMC
Bo Bet

0647434481
Scientific
Amsterdam UMC, location AMC
Bo Bet

0647434481

Eligibility criteria

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

Inclusion criteria

1. Singleton or twin pregnancy 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 years 2. Insufficient knowlegde 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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	16-04-2021
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 55184
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9494
CCMO	NL74879.018.21
OMON	NL-OMON55184

Study results