Long-term effects of preterm birth and retinopathy of prematurity on anatomy and functionality of the eye in adults

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Primary Objective: Compare visual acuity between adults born prematurely and adults of general population born at full term.Secondary Objective(s): o Compare other anatomical and functional ocular outcomes (retina, macula thickness, refraction,...

Ethical review	Approved WMO
Status	Pending
Health condition type	Eye disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON57302

Source
ToetsingOnline

Brief title
Long-term ophthalmic outcomes in ex-premature infants (LTOO-XP)

Condition

- Eye disorders NEC

Synonym
retrolental fibroplasia (RLF), Terry syndrome

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: Long term outcomes, Preterm birth, Retinopathy of prematurity, Visual acuity

Outcome measures

Primary outcome

The main study parameter is best corrected visual acuity (VA) in LogMAR.

Secondary outcome

Secondary study parameters include:

• Refraction

• Axial eye length

• Intra-ocular pressure (IOP)

• Anterior chamber depth

• Macula thickness

• Lens thickness

• Presence of ophthalmological diagnoses such as amblyopia or strabismus

• Visual field abnormalities

• Anatomical abnormalities of the retina (OCT images)

• Relevant (ophthalmological) medical history/ophthalmological diagnoses in the

past

• Self-reported health/activity (questionnaire)

Study description

Background summary

Every year, around 18.000 children in the Netherlands are born prematurely, which means that they were born before 37 weeks gestational age. The WHO

defines three different categories of prematurity: moderate to late preterm (32-37 weeks), very preterm (<32-28 weeks), and extremely preterm (<28 weeks). Preterm birth is associated with numerous health problems, which can have both short-term and long-term consequences on the development of the child. A relatively rare complication of (very or extreme) preterm birth is lifelong visual impairment or blindness due to retinal detachment as a result of retinopathy of prematurity (ROP). ROP is a vasoproliferative condition that affects the vessels in the retina. An inventory study shows that 305 children were diagnosed with ROP in the Netherlands in 2017. The majority of these children experienced spontaneous regression of the condition, but 13% of cases required treatment to prevent retinal detachment. In the long-term, ROP predisposes for ocular conditions such as visual field abnormalities, refractive error, strabismus, amblyopia, glaucoma and retinal detachment. However, research also indicates that prematurity, regardless of ROP diagnosis, can also be associated with adverse ophthalmological outcomes such as refractive error, strabismus, amblyopia and cerebral visual impairment (CVI). Although there are various publications on the ophthalmological outcomes of ROP and prematurity at school-age, less is known about these outcomes in the adult population of ex-prematures, especially relative to the general population of adults without a history of preterm birth. In this study we want to investigate the anatomy and functionality of the eye in adults who were born preterm between 1991 and 2006, and make the comparison with ocular outcomes in the general population of adults born at full term. In addition, we will investigate differences in outcomes between adults born prematurely with and without a history of ROP, and investigate differences in outcomes between treated and spontaneously regressed ROP.

Study objective

Primary Objective:

Compare visual acuity between adults born prematurely and adults of general population born at full term.

Secondary Objective(s):
o Compare other anatomical and functional ocular outcomes (retina, macula thickness, refraction, axial eye length, intra-ocular pressure (IOP), anterior chamber depth, strabismus, amblyopia) between adults born prematurely and adults of general population born at full term.
o Compare anatomical and functional ocular outcomes of adults born prematurely with and without any form of ROP.
o Compare anatomical and functional ocular outcomes of adults born prematurely with spontaneously regressed ROP versus treated ROP.

Study design

This study is designed as a comparative cross-sectional study. We invite adults who were born prematurely between 1991 and 2006 and were admitted to the neonatology unit at Erasmus MC for a scheduled eye exam at our ophthalmology department. Outcomes of this exam will then be analyzed and compared to the outcomes of a control population of adults born full term. Controls will be sourced from the Generation R study. Generation R is a prospective longitudinal cohort study that investigates development and health from fetal life until young adulthood in children born April 2002-January 2006 in Rotterdam, the Netherlands. Participants of the Generation R study have been invited for medical examinations, including an eye exam, every 3-4 years.

Study burden and risks

There are no explicit benefits for the participating subjects, aside from receiving a routine eye exam, which could also be interpreted as a burden. Subjects make one visit to Erasmus MC for an eye examination. This visit is expected to take one hour and a half. Travel costs are reimbursed and participants receive a compensation of 25 euros for their participation. Routine eye examination does not harm participating subjects and is generally free of substantial risks. The mydriatic and cylcoplegic eye drops used can also cause temporary discomfort, with the most common side effects being mild stinging feeling in the eye, temporary blurred vision, and eye sensitivity to light. Participants are informed about these and other possible side effects in the information letter. There could be accidental findings; participants are informed of accidental findings that are clinically relevant and require further diagnostics, prevention or treatment. The participation of the described population is crucial to get a better understanding of the lasting ophthalmic effects of preterm birth and ROP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Subject was born with gestational age < 32 weeks or born with birthweight <1500 gram or exposed to >40% O2 for > 3 days.
2. Subject was admitted to the NICU at Erasmus MC between 1991 and 2006.
Healthy controls are from the Generation R study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Subject has passed away before the start of this study
2. Subject resides outside of the Netherlands
3. Subject has a physical or mental disability that makes it impossible to participate in a routine eye exam, or has a disability that classifies the subject as an incapacitated adult.
For healthy controls, Generation R study subjects that were born preterm (<37 weeks) are excluded.

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-02-2025
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-02-2025
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
ClinicalTrials.gov	NCT06649513

Register	ID
CCMO	NL87522.078.24