Neurodevelopmental Outcomes and Morbidities of Moderate and Late Preterm Children at the Age of 9 Years - The Alkmaar MLPTI Cohort Study

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To examine cognition, motor function, executive functions, speech and language development, behaviour, psychosocial functioning, academic achievement, physical morbidities and growth of MLPTI at the age of 9 years and correlate this with BSID-III-NL...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53576

Source
ToetsingOnline

Brief title
The Alkmaar MLPTI Cohort study

Condition

- Other condition

Synonym
premature birth, Preterm birth

Health condition

Neonatologie, ontwikkeling, gedrag

Research involving

Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: NWZ-subsidie en NutriSociety

Intervention

Keyword: Growth, Moderate and late preterm infants, Morbidities, Neurodevelopmental outcomes

Outcome measures

Primary outcome

The main study parameters are the IQ-scores, motoric scores of the MABC, executive functions of the EMMA Toolbox and speech- and language-developmental scores of the CELF-5-NL and CCC-2-NL.

Secondary outcome

Secondary outcome parameters are CITO-scores, the behavioural and psychosocial outcomes of the CBCL and the SDQ, the presence of morbidities, the growth pattern and blood pressure. Other outcome parameters are the relation between the 9-year outcomes and the BSID-III scores at the age of 2, and the differences between the MLPTI and the control group. Furthermore, we aim to determine the relation between growth and body composition in the first two years of life and the waist circumference, growth parameters and blood pressure at the age of 9 years.

Study description

Background summary

Recent studies indicate that moderate and late preterm infants (MLPTI, gestational age (GA) 32-36 weeks) are at risk of lower IQ scores, behavioural problems and attention disorders and decreased school performances at the age of 6 to 10 years. One recent study correlated these attention problems at the age of 6 with outcomes of the Bayley Scales of Infant and Toddler Development (BSID-III-NL) performed at the age of 2. These recent findings are in contrast with the long-thought theory that MLPTI have the same outcomes as full-term children. Since the number of studies performed on this group is limited and the developmental outcomes of MLPTI remains a subject of debate, more prospective data are necessary to prove whether these children are truly at risk of impaired outcomes. The study with this cohort performed at the age of 2 years did not find an impaired outcome on the BSID-III-NL scores. However, it is questionable whether this test is sensitive enough to find small differences and if problems are more obvious at school age. Furthermore, we should investigate the possibility of early detection of these impaired outcomes.

Study objective

To examine cognition, motor function, executive functions, speech and language development, behaviour, psychosocial functioning, academic achievement, physical morbidities and growth of MLPTI at the age of 9 years and correlate this with BSID-III-NL scores, growth parameters and body composition at the age of 2 years.

Study design

This study will be a prospective open, non-therapeutic exploratory cohort study and can be seen as a continuation on the study with protocol identification number NL50800.094.14, performed in the NWZ Alkmaar between 2014 and 2016. This was a study on growth and neurodevelopment of MLPTI in the first 2 years of life.

Study burden and risks

The burden consist of coming to the outpatient clinic for one schoolday to perform the aforementioned tests. The WISC-V, MABC and CBCL are part of standard care in very and extreme preterm children (GA<32 weeks) at the age of 8, have no risks and are a minimal burden. The Emma Toolbox and CELF-5-NL are not part of standard care, but also developmental tests with no risk and minimal burden and are widely used in different international studies. The tests performed during this visit will take up to four and a half hours in total (including a break). There is also an additional burden for the parents, since they will be asked to fill in questionnaires, which takes up to an hour in total. This study cannot be performed in an adult group of patients, since we explicitly want to explore these outcomes of MLPT at the age of 9.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. The participant is born in or transferred to the NWZ Alkmaar between January 1st, 2014 and April 18th, 2016 (the inclusion time of trial NL50800.094.14)
2. The participant born at a gestational age from 32 to 35+6 weeks
3. The participant received follow-up conform the trial with trial-number NL50800.094.14
4. Both parents of the participant have given informed consent to participate in this trial
OR (Control group)
1. The participant has a brother, sister or friend who meets aforementioned inclusion criteria.
2. The participant is between 8 and 10 years old when participating in this study.
3. The participant is a child that lives < 20 km of Alkmaar and is

recruited at the 9 years
vaccination of the GGD
4. The participant is related to an employee of the North West Hospital and living < 20 km of
Alkmaar
5. The participant is not born preterm or admitted to a neonatology ward post-partum and

Exclusion criteria

1. The participant*s parents are not able to fill out questionnaires or perform tests in Dutch 2. The participant has a severe developmental disorder and is thereby not able to perform the tests 3. The participant is not able to come to the outpatient clinic to do the tests OR (Control Group) 1. The participant is born with a GA < 37 weeks 2. The participant has a severe developmental disorder and is thereby not able to perform the tests

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:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2023
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2024
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL82197.029.22
Other	Trialregister NTR 5563