Biomarkers in Infants at Risk of Developmental disorders (BIRD) - IMP-SINDA Follow-up Study II

Published: 25-02-2021
Last updated: 24-08-2024

Our primary objective is to investigate the relation between atypical IMP and SINDA scores in infancy and symptoms of DCD at 4-5 years of age measured with the Movement Assessment Battery for Children - 2nd edition. The relation will also be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON51168

Source
ToetsingOnline

Brief title
BIRD II

Condition

- Neurological disorders NEC
- Developmental disorders NEC

Synonym
Attention Deficit Hyperactivity Disorder (ADHD, Autism (ASD, 'clumsiness'), Developmental Coordination Disorder (DCD, 'hyperactivity'), Intellectual disability ('mental retardation' and 'learning disability'), 'problems in social skills')

Research involving
Human

Sponsors and support

Primary sponsor: Psychiatrie
Source(s) of monetary or material Support: door Accare Child Study Center en subside van de Cornelia Stichting (¤15.000). Tevens subside aangevraagd bij de Stichting KinderNeuroPsychologie Noord-Nederland.

Intervention

Keyword: Biomarkers, Early detection, Infant neuromotor assessment, Neurodevelopmental disorders

Outcome measures

Primary outcome

Our parameters are scores obtained through assessments and questionnaires to

assess symptoms of the previous mentioned developmental disorders.

Our main study parameter is the score on the *Movement Assessment Battery for

Children - 2nd edition* (MABC-2); a valid and reliable motor assessment for

children aged 3 to 16 years which is developed to assess DCD. The scores of the

MABC-2 are dichotomized as *at risk of DCD* (<=16th percentile) or not.

Secondary outcome

- The Developmental Coordination Disorder Questionnaire-revised (DCDQ): to

assist in the identification of DCD in children.

- The Conners* Rating Scale-Revised (CRS-R) for parents and teachers: to assess

ADHD and most common co-morbid problems as reported by teachers, parents or

other caregivers.

- Wechsler Preschool and Primary Scale of Intelligence - IV (WPPSI-IV NL): a

test of intellectual ability for children aged 2.5 to 7 years.

- Social Responsiveness Scale (SRS-2): this widely used scale identifies social impairment associated with ASD and quantifies its severity.
- The Sensory Profile (SP-NL): a measure of children*s responses to sensory events in daily life to assess sensory stimulus information processing difficulties.
- Minor Neurological Dysfunction (MND) assessment: neurological age-specific examination to detect minor neurological dysfunction.
- Strengths and Difficulties Questionnaire (SDQ) this short behavioural screening instrument is suitable for children aged 2 to 17 years old and aims to identify psychosocial problems in children.

Other study parameters are:
- All relevant information obtained during the earlier stages of the IMP-SINDA study or BIRD I study concerning pre-, peri- and neonatal factors, and behaviour and developmental factors assessed with the online questionnaire in BIRD 1. Relevant information includes the general questionnaire on presence of illnesses, medication use and visual and auditory problems, known developmental problems, current school of the children, socio-economic background, psychiatric and developmental disorders in the parents.

Study description

Background summary

There is an evident delay between parents* first concerns and confirmation of a neurodevelopmental disorder, such as autism spectrum disorder (ASD), attention

deficit hyperactivity disorder (ADHD), developmental coordination disorder (DCD), and intellectual disability. This is due to a lack of knowledge on signs in infancy of these disorders. As a consequence, concerns of parents remain unheard and interventions start late. In our previous study (IMP-SINDA norms study) 1700 infants aged 2-18 months were assessed with two new infant neurodevelopmental assessments: the Infant Motor Profile (IMP) and the Standardized Infant NeuroDevelopmental Assessment (SINDA). In the current study we will continue in the same cohort of children, and investigate the association between their neurodevelopmental condition at age 2-18 months as measured with IMP and SINDA with their neurodevelopmental, emotional, and behavioural functioning when they are 4-5 years of age.
We expect that atypical IMP-SINDA scores in infancy are associated with symptoms of developmental disorders at 4-5 years of age.

Study objective

Our primary objective is to investigate the relation between atypical IMP and SINDA scores in infancy and symptoms of DCD at 4-5 years of age measured with the Movement Assessment Battery for Children - 2nd edition. The relation will also be expressed in terms of predictive values (sensitivity, specificity, negative and positive predictive values.

Secondary objectives:
- To investigate the relation between atypical IMP and SINDA scores in infancy and symptoms of ADHD at 4-5 years of age.
- To investigate the relation between atypical IMP and SINDA scores in infancy and symptoms of ASD at 4-5 years of age.
- To investigate the relation between atypical IMP and SINDA scores in infancy and intellectual disability at 4-5 years of age.
- To investigate the relation between atypical IMP and SINDA scores in infancy and sensory stimulus information processing difficulties at 4-5 years of age.

Study design

Nested case-control study, drawn from the population of a cross-sectional study in the general population.

Study burden and risks

The children will be assessed once, at the Child-lab at the Institute for Developmental Neurology (UMCG) or at the child*s home. The assessment has the form of play. Children mostly enjoy the assessments, but it may happen that a child is anxious or is not in the mood for an assessment. If the child shows signs of protest, the assessment will be stopped. It is discussed with the parents whether the assessment will be resumed or it may be rescheduled to a later point in time or will be cancelled. During the assessment of the child,

parents will fill out a questionnaire on signs of developmental disorders (60 min). The entire assessment will take about 90 minutes. There are no risks associated with participation. The benefit of the study is that it will result in knowledge about neurodevelopmental signs of developmental disorders and therefore enable early detection and intervention of these disorders.

Contacts

Public
Selecteer

Hanzeplein 1 Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Selecteer

Hanzeplein 1 Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Subject has participated in the IMP-SINDA norms study (METc 2016.294)
- Age at inclusion between 4 and 5.5 years

Exclusion criteria

There are no criteria to exclude a potential subject from participation in this study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2021
Enrollment:	735
Type:	Actual

Ethics review

Approved WMO

Date:	25-02-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL75617.042.20