Neurological signs in very high-risk infants and developmental outcome at school age

Published: 18-09-2017
Last updated: 11-07-2024

To improve prediction of neurological and functional outcome at school age in infants at high risk of cerebral palsy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON50365

Source
ToetsingOnline

Brief title
Early neurological signs and outcome

Condition

- Congenital and peripartum neurological conditions

Synonym
cerebral palsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cerebral palsy, developmental outcome, high-risk infants, neurological signs

Outcome measures

Primary outcome

Vineland-II

For the study of the kneejerk with the control group: the latency to the phasic

response to the kneen jerk

Secondary outcome

Neurological, motor, visual, cognitive and behavioural outcome

Study description

Background summary

Cerebral Palsy (CP) is one of the most common neurological disorders in childhood, with a Western European incidence above 2 per 1000 live births. Early identification of infants at risk of CP is desirable in order to provide early intervention, in a phase when the brain is most plastic, and for family counselling. We recently reported associations between both atypical pupillary light responses and knee jerk responses in infancy and neurological outcome at 21 months corrected age in infants at high risk for CP. As the brain continues to develop throughout childhood, associations between early risk factors and later outcome may change with age. This means that associations between risk factors and developmental outcome at early age may disappear when the child grows older. But also the reverse may occur: associations between early risk factors and developmental outcome may get stronger as dysfunctions may emerge when the brain develops new functions. The latter occurs often in high-risk infants. The aim of the present study is therefore to determine whether neurological signs in infancy, such as an atypical pupillary light response and atypical knee jerk responses are related to neurological and functional outcome at school age.

For the amendment: the first data of the follow-up study indicate that the responses to the kneejerk are not only deviant in children with CP (which has

been described in the literature), but proabably also in the children with an early lesion of the brain without CP (which would be a novel finding). In order to be able to describe and explain such findings we extend the knee-jerk part of the study with a group of 25 typically developing peers (7-10 years of age) without an early lesion of the brain.

Study objective

To improve prediction of neurological and functional outcome at school age in infants at high risk of cerebral palsy.

Study design

Cohort study

Study burden and risks

The children will be assessed once. The assessment will take place at the child*s home and the tests applied are child friendly. If the child - for whatever reason - does not wish to cooperate anymore, the assessment is stopped. It is discussed with the parents whether it is possible to reschedule the appointment at a later point in time. To minimize the assessment time and burden for the children, parents will also fill in questionnaires about their child*s functioning. The benefit of the study is improving early prediction of developmental outcome in high-risk infants. The data can only be obtained by studying these high-risk infants. Benefits of participation for child and family consist of getting detailed information on the child*s current developmental status - if desired.

Control group: the assessment takes about 45 minutes. The parents fill out a short questionnaire (10 minutes).

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1

Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

For the patients: participation in the LEARN2MOVE 0-2years project (L2M; n=43). Inclusion criteria for the original LEARN2MOVE 0-2 years project were age zero to nine months CA at enrolment and the presence of at least one of the following conditions:
(1) cystic periventricular leukomalacia,
(2) parenchymal lesion of the brain,
(3) severe neonatal hypoxic-ischaemic encephalopathy with brain lesions on MRI,
(4) neurological dysfunctions suggestive of the development of CP.
For the control group:
(1) typically developing
(2) age 7-10 years
(3) attending mainstream education

Exclusion criteria

For the patients: Exclusion criteria of the LEARN2MOVE 0-2 years project were:
- Children with severe congenital disorders
- Caregivers having insufficient understanding of the Dutch language
For the controls:
- presence of a complicated neonatal history
- presence of a neurodevelopmental disorder, such as cerebral palsy, developmental coordination disorder, autism spectrum disorder, learning disability, or attention deficit hyperactivity disorder
- Presence of the complex form of minor neurological dysfunction (MND)

- Caregivers having insufficient understanding of the Dutch language

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2017
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-10-2020
Application type:	Amendment
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	NL61985.042.17