Norm data for the Infant Motor Profile (IMP) and the Standardized Infant NeuroDevelopmental Assessment (SINDA)

Published: 07-11-2016
Last updated: 14-04-2024

to generate norm data of the IMP and SINDA.

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

Summary

ID

NL-OMON43209

Source
ToetsingOnline

Brief title
Norm data for the IMP and SINDA

Condition

- Congenital and peripartum neurological conditions

Synonym
collection of norm data, so mostly typical development is assessed

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Cornelia Stichting en Stichting Ontwikkelingsneurofysiologie Groningen

Intervention

Keyword: infant developmental assessment, Infant Motor Profile, infant neuromotor assessment, norms

Outcome measures

Primary outcome

IMP-scores (total score, and five domainscores (variation, adaptability,

symmetry, fluency, performance)

Secondary outcome

SINDA scores (neuromotor and developmental scores)

Study description

Background summary

Recently our institute developed two measurement instruments for the detection of developmental disorders in infants, the Infant Motor Profile (IMP) and the Standardized Infant NeuroDevelopmental Assessment (SINDA). Detection of high risk for developmental disorders at early age is a prerequisite for the implementation of early intervention at young age when there is maximum plasticity of the nervous system and chances for improvement are highest.
The IMP is a qualitative assessment of motor behaviour of infants aged 3 to 18 months. In addition to being a tool for the detection of infants at high risk for developmental disorders, the IMP may be used to monitor changes in motor development and the effect of early intervention. The SINDA is a tool for paediatricians to assess infant development at 2 to 12 months. SINDA has a neuromotor and a developmental scale.
For the implementation of the IMP and SINDA in clinical practise normdata are a prerequisite.

Study objective

to generate norm data of the IMP and SINDA.

Study design

In order to generate norm data 1700 infants aged 2 to 18 months will be assessed (100 infants per *month age*). The infants will be recruited via

well-baby clinics and day care centres in the three Northern provinces of the Netherlands and via the website of the Kinderacademie (www.dekinderacademie.com). The sample needs to be representative for the Dutch population in terms of sex, socio-econonmic and ethnic background. The assessment will consist of an IMP and SINDA assessment and the collection of demographic characteristics. The data will be used to compute developmental curves with cut offs for typical, borderline and atypical development.
The infants will be recruited by the Kinderacademie, that has large experience in the generation of normdata for paediatric tests. The infants will be assessed by assessors of the Kinderacademie and assessors of the Institute of Developmental Neurology of the UMCG.

Study burden and risks

The study is not associated with risk for the infant. The assessment of the infant consists of play activities and the performance of routine neurological actions such as the pull-to-sit manoeuvre and the assessment of tendon reflexes. This means that study's burden consists of a time investment of parents and infant. We consider this investment justified as it ultimately will result in norm data for two instruments, that currently are implemented in clinical practise.

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

The child lives in one of the three northern provinces of The Netherlands
Age at inclusion between 2 and 18 months
Parents or legal representatives will provide written informed consent

Exclusion criteria

A potential subject who meets any one of the following criteria will be excluded from participation in this study:
Severe illness precluding the assessment, such as complex congenital heart disorders with insufficient oxygen saturation
Parents have insufficient understanding of the Dutch language to be able to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2017
Enrollment:	1700
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2016
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
Other	Aangemeld bij NTR - we wachten nog op een nummer
CCMO	NL58069.042.16