

Follow-Up Neonatology study

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By the use of inertial measurement units and the tablet, a more sensitive and objective measurement of motor skills will be obtained.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21095

Bron

NTR

Verkorte titel

FUN study

Aandoening

premature born;

Ondersteuning

Primaire sponsor: Orthopedisch Centrum Oost Nederland

Overige ondersteuning: Pioneers in Health Care

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Motor skill assessment by the use of inertial measurement units.

Toelichting onderzoek

Achtergrond van het onderzoek

In the Netherlands, 7% of the children are born prematurely (defined as a gestational age of below 37 weeks). Despite the fact that the survival of this population has been improving over the past decades, the morbidity is still high. Developmental issues are common in this population, such as the development issues with the eyes, lungs or motor skills. One of the tools that can be used to follow-up on the motor skills is the Movement Assessment Battery for Children – 2 (MABC-2). The specificity of the MABC-2 is acceptable (88%), however, sensitivity is low (41%). In order to evaluate motor skills, a more objective, non-invasive and sensitive measurement is needed. The goal of this research is to increase the sensitivity and objectivity of the MABC-2 by measuring the MABC-2 balance and gross motor tasks with inertial measurement units. The MABC-2 fine motor coordination will be measured with a tablet.

Doel van het onderzoek

By the use of inertial measurement units and the tablet, a more sensitive and objective measurement of motor skills will be obtained.

Onderzoeksopzet

Two week prior to their appointment at the outpatient clinic, patients will receive the information letter.

The informed consent will be signed prior to the start of the measurements, during the appointment at the outpatient clinic.

Contactpersonen

Publiek

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Wetenschappelijk

Orthopedisch Centrum Oost Nederland
Emilie Klaver

088 708 3370

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a child must meet all of the following criteria:

- The age of the child is between 4 years (and 0 months) and 7 years (and 0 months)
- The child is born at the gestational age of 32 weeks or below.
- The child has a routinely scheduled Follow – Up Neonatology appointment at the out-patient clinic. This appointment combines pulmonary screening by a specialized sports physician with a consult of their neonatologist and a paediatric physiotherapist.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

The child is excluded if the child cannot execute tasks of the MABC-2.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	18-02-2019
Aantal proefpersonen:	20

Type:

Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:

15-02-2019

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7524
Ander register	METC Twente : K19-06

Resultaten