Brain Activity and Motor Behaviour in Infants

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To study the neural basis of i) general movements including the transition to the last phase of general movements, the fidgety movements, en ii) the transition from general movements into goal-directed movements using electromyography (EMG),...

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

Summary

ID

NL-OMON48157

Source
ToetsingOnline

Brief title
BAMBI

Condition

- Neurological disorders NEC

Synonym
developmental disorders, Healthy infants

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,de post-doc subsidie van Dr. Ying-Chin Wu (bron: Taiwanese Ministry of Science and Technology)

Intervention

Keyword: 3D-kinematics, EEG, EMG, General movements

Outcome measures

Primary outcome

Muscle coordination patterns (EMG-activity): especially duration of bursts,

degree of antagonist co-activation and EMG-EMG coherence

Secondary outcome

Corticomuscular (EEG-EMG) coherence, and kinematic characteristics, especially

intra-limb joint angle correlation.

Study description

Background summary

General movements (GMs) are present from early fetal life until 3-5 months corrected age. It is well known that the assessment of the quality of the GMs has predictive value in identifying infants at risk of cerebral palsy (CP) and other developmental disorders. Currently GM-quality is assessed by means of human Gestalt analysis of video recordings of GMs. Little is known on the neurodevelopmental organization, e.g., in terms of muscle coordination patterns and cortical activity, underlying both the presence of GMs and the transition of GMs to goal-directed activity.

Study objective

To study the neural basis of i) general movements including the transition to the last phase of general movements, the fidgety movements, en ii) the transition from general movements into goal-directed movements using electromyography (EMG), electroencephalograpy (EEG) and 3D-kinematic video data. This knowledge will facilitate the development of automatic movement analysis systems.

Study design

Longitudinal cohort study

Study burden and risks

The infants will be assessed 4 four times (at 1, 3, 5 and 18 months of age * the last assessment serves the documentation of developmental outcome). The assessments will take place at the babylab at the Institute of Developmental Neurology at the UMCG. If the infant is tired, crying or hungry, the assessment is stopped. It is discussed with the parents whether it is possible to reschedule the appointment at a later point in time. The data can only be obtained by studying infants. Benefits of participation for infant and family consist of getting detailed information on infant motor development in general and on the infant*s current developmental status * if desired.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy full-term infants, i.e. an infant born after a gestational age of at least 37 weeks without prenatal, perinatal or neonatal complications, younger than 1 month of age (first assessment at age of 1 month).

Exclusion criteria

Infants will be excluded from the study in case of:
- severe congenital abnormalities, such as serious congenital heart disorders or a chromosomal condition
- birthweight below the tenth percentile
- neurological abnormalities
- parents have insufficient understanding of the Dutch language

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):	11-11-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2019
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	NL68295.042.19