Characteristics of abnormal general movements and daily function at school age

Published: 02-07-2012
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To evaluate associations between specific characteristics of DA GMs around 3 months CA and daily function at 8 years.

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

Summary

ID

NL-OMON37586

Source
ToetsingOnline

Brief title
Abnormal GMs and function at school age

Condition

- Neurological disorders congenital

Synonym
developmental disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: developmental outcome, early prediction, GMs, school age

Outcome measures

Primary outcome

Motor skills domain of the Vineland Adaptive Behavior Scale (VABS)

Secondary outcome

- VABS domains: communication, daily life activities, socialization

- Developmental Coordination Disorder Questionnaire (DCD-Q)

- Child Behavior Check List (CBCL)

- additional information on specific learning disorders, need of special

school, psychiatric diagnoses.

In addition information is collected on

- parental coping behaviour by means of the Utrechtse Coping Lijst

- parental education and profession and family composition

- interventions which the child received

- medical history

Study description

Background summary

Definitely abnormal general movements (GMs) around 3 months corrected age (CA) indicate a high risk for developmental disorders, such as cerebral palsy (CP) or behavioural disorders. We recently reported that specific characteristics of definitely abnormal (DA) GMs around 3 months CA, such as the absence of *fidgety* movements and the presence of stiff movements, improve prediction of outcome at 18 months of age (Hamer et al. 2011). 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 (children *grow out* of their problem). 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, such as infants born preterm.
Therefore the present study aims to determine whether specific movement characteristics of general movements also improve prediction for impaired daily function at school age.

Study objective

To evaluate associations between specific characteristics of DA GMs around 3 months CA and daily function at 8 years.

Study design

Re-assessment of participants of a randomized controlled trial (RCT) on the effect of physiotherapeutic intervention in infancy (VIP-project). The participants of the VIP-project were included on the basis of presence of DA GMs around 3 months CA. The RCT indicated that intervention did not affect outcome at 18 months, which allows for pooling of the two groups to study associations between early motor characteristics and outcome at 8 years (in analogy to the previous study in which we demonstrated associations between characteristics of DA GMs and developmental outcome at 18 months; Hamer et al. 2011).

Study burden and risks

There are no risks associated with participation. Costs of the study are a limited time investment of parents and investigators.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Definitely abnormal GMs at 3 months corrected age, participant in the VIP-project (see protocol sections 3 and 4).

Exclusion criteria

In the VIP project children with severe congenital anomalies, such as serious congenital heart disorders, and infants whose caregivers had an inappropriate understanding of the Dutch language were excluded from the study.

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):	02-07-2012
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2012
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	ISRTCN52740878
CCMO	NL39954.042.12