General Anesthesia exposure and neurodevelopmental outcome in Pediatrics.

Published: 13-01-2020 Last updated: 10-04-2024

To investigate the impact of different levels of anesthesia exposure on children*s neurocognitive development and evaluate the concurrent validity of different methods to assess neurodevelopmental outcome.

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

Summary

ID

NL-OMON54873

Source ToetsingOnline

Brief title GAP trial

Condition

- Neurological disorders NEC
- Therapeutic procedures and supportive care NEC

Synonym brain development, Neurodevelopmental outcome

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W,Fonds van Stichting

Steun Emma

Intervention

Keyword: Anesthesia, Children, Neurodevelopmental outcome

Outcome measures

Primary outcome

Neurodevelopmental outcome (infant development, motor and cognitive development

and early attention) in children with a history of anesthesia exposure before

the age of 12 months.

Secondary outcome

Concurrent, convergent and divergent validity of eye-tracking relative to

traditional measures (Ages & Stages Questionnaire and Bayley Scales of Infant

Development) of neurodevelopmental outcome in children with a history of

anesthesia exposure before the age of 12 months.

Study description

Background summary

Recent evidence indicates that prolonged or repeated anesthesia threaten neurodevelopment. Therefore, we deem that it is crucial to assess the impact of different levels of anesthesia exposure between groups on neurodevelopmental outcome. The Ages and Stages questionnaire and Bayley Scale are well-known and widely used methods to accurately measure neurodevelopment, i.e. early global motor and cognitive development. Eye tracking is eminently suitable to assess early neurocognitive development, more specifically the infant*s early attentional system which is of paramount importance for later cognitive development.

Study objective

To investigate the impact of different levels of anesthesia exposure on children*s neurocognitive development and evaluate the concurrent validity of

different methods to assess neurodevelopmental outcome.

Study design

Prospective observational study. Neurodevelopmental outcome will be assessed in children with a history of different levels of anesthesia exposure before the age of 12 months using the Ages & Stages Questionnaire, Bayley Scales of Infant Development and eye-tracking metrics.

Study burden and risks

There are no additional risks associated with participation in this study and the burden can be considered minimal. This study assesses whether anesthesia exposure is harmful to children*s neurocognitive development. Therefore, this study can only be performed in this group of minors.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years) Babies and toddlers (28 days-23 months)

Inclusion criteria

- Infants aged 12 months
- Anesthesia exposure before the age of 12 months

Exclusion criteria

Children with comorbid conditions affecting structure and/or function of the central nervous system (e.g. premature birth) will be excluded from participation in this study.

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

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2020
Enrollment:	70
Туре:	Actual

Ethics review

Approved WMO

Date:	13-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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 CCMO Other

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