General Anesthesia exposure and neurodevelopmental outcome in Pediatric

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26844

Source
Nationaal Trial Register

Brief title
GAP-trial

Health condition

Surgeries related to dDuodenal-jejunal-ileal atresia repairs, anorectal malformation, Hirschsprung disease and/or inguinal hernia

Sponsors and support

Primary sponsor: Emma Children’s Hospital, Amsterdam UMC.
Source(s) of monetary or material Support: Stichting Steun Emma Kinderziekenhuis

Intervention

Outcome measures

Primary outcome

Neurocognitive development as measured using eye-tracking metrics

Secondary outcome

a. Conventional measures of neurocognitive development (Ages & Stages Questionnaire and Bayley Scales of Infant Development)
b. Total anesthesia time. Surgery and anesthesia time will be recorded by the (fellow) surgeon performing the operation(s). When multiple procedures are carried out, durations will be combined and these results will be retrieved during analysis of the data.

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. For this prospective study, children with and without a history of general anesthesia exposure during pediatric surgery are recruited at the age of 12 months to measure neurodevelopment at the outpatient clinic using the Ages & Stages Questionnaire, the Bayley Scales of Infant Development and the Eye-tracking paradigms.

Study objective

Anesthesia exposure before the age of 12 months old has a negative impact on neurocognitive development.

Study design

Participation in this trial consists of one (extra) visit to the outpatient clinic. For most patients, this will be scheduled during their regular follow-up visit at 12 months (± four weeks) of age.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: age 12 months (± four weeks) with a history of general anesthesia exposure (patient group) or without a history of general anesthesia (healthy controls)

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-10-2020
Application type:	First submission

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
NTR-new	NL8937
Other	METc Amsterdam UMC, location AMC : METC 2019_249

Study results