The effects of anaesthesia on neurodevelopmental outcome and apnoe in infants: the GAS study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38102

Source
ToetsingOnline

Brief title
GAS study

Condition

- Other condition
- Congenital and peripartum neurological conditions

Synonym
neurodevelopmental outcome

Health condition

anesthesiologie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Het internationale onderzoek wordt betaald door NIHR HTA UK en CIHR Canada. In Nederland wordt het onderzoek door de het ziekenhuizen zelf betaald.

Intervention

Keyword: Anesthesia, Infants, neurodevelopmental outcome, Spinal

Outcome measures

Primary outcome

The primary outcome will be the WPPSI-III Full Scale IQ score at 5 years

corrected age.

Secondary outcome

1) Other measures of neurodevelopmental outcome

2) Incidence of apnoea

3) Other outcomes relating to anaesthesia group

4) Incidental outcomes not related to choice of anaesthesia

Study description

Background summary

Recent animal data has provided evidence to suggest that several commonly used anaesthetic agents (including volatile anaesthetic agents) may be neurotoxic to the developing brain.

Study objective

The primary objective of this trial is to determine whether different types of anaesthesia [regional versus general] given to infants undergoing inguinal hernia repair result in equivalent neurodevelopmental outcomes. Secondary objectives are to describe the frequency and characteristics of apnoea in the post-operative period after both regional and general anaesthesia for inguinal

hernia repair in infants, and determine the factors associated with apnoea.

Study design

Prospective, observer blind, multi-site, randomised, controlled, equivalence trial.

Intervention

The general anaesthesia group will receive sevoflurane for maintenance and induction. The airway can be maintained with a face mask, laryngeal mask or endotracheal tube, with or without neuromuscular blocking agents. Analgesia can be supplied with a caudal or ilioinguinal nerve block with bupivacaine up to a maximum dose of 2.5 mg/kg.

The regional group will have no sedative agents. The regional blockade may be with spinal block alone, spinal block with caudal block, spinal with ilioinguinal block or caudal alone. A maximum dose of 2.5 mg/kg of bupivacaine can be used.

Study burden and risks

There is a strong argument to believe equipoise exists in this trial. Awake regional and general anaesthesia are both accepted standards of care for inguinal hernia repair in children. Regional anaesthesia may be more technically demanding and preferences for one or the other may vary depending on the experience of the paediatric anaesthetist. In younger patients regional anaesthesia may be associated with less apnoea than general anaesthesia but this may be less apparent with the newer general anaesthesia agents. Similarly although there is animal data for toxicity, the evidence for risk of general anaesthesia is sufficiently weak to accept general anaesthesia as an arm in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Any infant scheduled for unilateral or bilateral inguinal hernia repair (with or without circumcision)
Any infant whose gestational age (GA) is 26 weeks or more
Any infant whose post-menstrual age (PMA) is up to 60 weeks.

Exclusion criteria

1. Any child older than 60 weeks post-menstrual age
2. Any child born at less than 26 weeks gestation
3. Any contraindication to general or spinal/caudal anaesthesia (for example: neuromuscular disorder or coagulopathy)
4. Pre-operative ventilation immediately prior to surgery
5. Congenital heart disease that has required surgery or will require surgery or which requires ongoing pharmacotherapy
6. Known chromosomal abnormality or any other known acquired or congenital abnormalities (apart from prematurity) which are likely to affect development
7. Children where follow-up would be difficult for geographic or social reasons
8. Families where Dutch is not the language spoken at home
9. Known neurological injury such as cystic periventricular leukomalacia (PVL), or grade 3 or 4 intra-ventricular haemorrhage (IVH) (+/- post-haemorrhage ventricular dilatation)
10. Previous exposure to volatile anaesthesia or benzodiazepines as a neonate or in the third trimester in utero

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2011
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bupivacaine
Generic name:	Bupivacaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sevoflurane
Generic name:	Sevoflurane
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	27-04-2011
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2006-006295-37-NL
ISRCTN	ISRCTN12437565
CCMO	NL32531.041.10