Timing of inguinal hernia repair in premature infants: A randomized trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47652

Source
ToetsingOnline

Brief title
HIP- trial

Condition

- Soft tissue therapeutic procedures

Synonym
groin hernia, Inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,National Institute of Health (Verenigde Staten)

Intervention

Keyword: Inguinal Hernia, Neurodevelopmental outcome, Premature/preterm infants

Outcome measures

Primary outcome

The primary outcome measure is the proportion of infants with * 1 Serious Adverse Event (SAE), measured from enrolment through 10 months after enrolment.

Secondary outcome

1. Compare the overall safety of early and late IH repair with respect to neurodevelopmental outcome assessed with intra-operative measurements and at 22-26 months corrected age (at selected sites with well-established follow up programs).

2. Using Bayesian and frequentist analyses, evaluate specific hypotheses about patient characteristics that may influence the relative safety of early and late IH repair.

3. To conduct the HIP Trial in an exemplary manner and thereby promote the newly established American pediatric Surgery Research Collaborative (pedSRC) as an ongoing research network

Study description

Background summary

Very few commonly used neonatal surgical therapies have been evaluated to determine their safety. Due to the lack of evidence, current decision- making regarding neonatal surgery relies primarily on the preferences of the surgeons and neonatologists. As IH repair in premature infants is the most commonly

performed operation in premature infants with an associated morbidity of 30-40%, we have chosen to focus on this group. It is unknown whether the IH repair prior to discharge home or delayed IH repair is the safer approach in premature infants.

Study objective

The objective of this study is to determine whether early inguinal hernia repair (prior to discharge home) or late inguinal hernia repair (approximately 5 months after discharge home) is the safer surgical approach for premature infants who are diagnosed with an inguinal hernia while in the NICU. In order to do so, several centres throughout the Netherlands will be collaborating with a multicentre RCT conducted by the Vanderbilt University Medical Center. The Erasmus MC will be the coordinating center in the Netherlands.

Study design

International multicentre randomized pragmatic clinical trial. Randomization will be stratified according to site and GA (gestational age) strata (<28 weeks and * 28 weeks estimated GA) to further ensure as equal risk groups as possible.

Intervention

The early inguinal hernia repair group will be operated on before discharge home (~38 weeks PMA (post menstrual age)). The late inguinal hernia repair group in comparison will be operated on 5 months after discharge home (60 weeks PMA).

Study burden and risks

Two additional assessments will take place in the postoperative period (one as an outpatient visit and one by phone). After this the patient will enter the follow-up phase for neurodevelopmental assessment. This requires additional neurodevelopmental assessments, which will be combined with standard of care visits to assure minimal burden for the participants and caretakers. The burden of the eye-tracking examination is minimal as it is non- invasive, there will be no intervention and it does not require active participation of the child. The eye-tracking session will take 15 minutes with a maximum op to 30 minutes. The Bayley Score of Infant Development wille be performed af 2 years of age and the assessement will take up to 90 minutes.

Risk related to timing of operation
Current decision-making regarding inguinal hernia repair relies primarily on the preferences of the surgeons and neonatologists partly due to lack of evidence. Current care differs from early repair (before discharge) and late

repair (> 60 PMA). There is a void in our clinical knowledge regarding safety and optimal time of operation. For early repair there may be greater risk of complications from general anesthesia and the operation may be more challenging to perform. In the late repair group there may be risk of hernia incarceration and strangulation of the trapped bowel which could result in emergency surgery.

Anaesthesia risk
The majority of the premature infants undergoing IH repair have general anaesthesia. Multiple studies have identified an association between general anaesthesia and neurotoxicity, however none of these studies were randomized clinical trials and have serious limitations as such. Inguinal hernia repair is considered the standard and required treatment for infants with an inguinal hernia. Anaesthesia is a necessary component of this surgical treatment.

The inguinal hernia is anatomically different in early childhood than it is at a later age. It also is more frequently seen in premature infants (~50%) and requires surgical care. The inguinal hernia, the operation and the associated age related problems are specific for this patient group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1) gestational age (GA)<37 weeks
2) diagnosed with inguinal hernia by pediatric surgeon
3) diagnosed during hospital stay
4) Parental informed consent

Exclusion criteria

1) Infant is undergoing another operative procedure and IH repair is planned as a secondary procedure
2) Associated factor impacts timing of IH repair
3) Known major congenital anomaly or chromosomal abnormality (specified in protocol)
4) Family unable / unwilling to return for follow up or are not willing to participate if the patient is randomized for late IH repair;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	100

Type:	Anticipated

Ethics review

Approved WMO Date:	26-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT01678638
CCMO	NL56310.078.18