Open vs Laparoscopic hernia repair in children: A randomized controlled trial

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To study the most relevant outcome measures and a cost-effectiveness analysis of laparoscopic PIRS technique compared to open hernia repair in infants aged 6 months to 16 years of age with a primary unilateral inguinal hernia

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56268

Source
ToetsingOnline

Brief title
HERNIIA II trial: Hernia Endoscopic oR opeN repair In chIldren Analysis.

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
groin rupture, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: inguinal hernia, laparoscopic, open, paediatric

Outcome measures

Primary outcome

Primary endpoint: Number of operations related to inguinal hernia within two year after inguinal hernia repair.

Secondary outcome

Duration of surgery, operative and postoperative complications, use of different anaesthetic techniques, duration of hospital admission, postoperative pain, time to full recovery, CPPV-rate, cosmetic appearance and cost-effectiveness (health care and social costs).

Study description

Background summary

Paediatric inguinal hernia repair is one of the most frequently performed operations in children. Treatment is necessary because of the risk of incarceration of bowel, testis or ovary, which occurs in approximately 3-16% of children with inguinal hernia. Open inguinal hernia repair is the most performed treatment strategy in children, however, laparoscopic inguinal hernia repair in children is increasingly performed as it allows easy contralateral inspection and potentially results in shorter operation time and fewer complications. Evidence regarding the superiority of laparoscopic versus open hernia repair is lacking in children.

Study objective

To study the most relevant outcome measures and a cost-effectiveness analysis of laparoscopic PIRS technique compared to open hernia repair in infants aged 6 months to 16 years of age with a primary unilateral inguinal hernia

Study design

A randomized controlled trial. Infants that need to undergo inguinal hernia repair will be randomized to either open or laparoscopic correction.

Intervention

Open hernia repair or laparoscopic Percutaneous Internal Ring Sutering (PIRS) repair

Study burden and risks

Both the open and PIRS technique are commonly used techniques in paediatric inguinal hernia repair and are dependent of the surgeon performing the procedure. Therefore, no extra burden of risk exist regarding this study. Both treatment strategies are currently performed in children with unilateral inguinal hernia who need to undergo hernia repair. Consequently, there are no additional risks for subjects of this study and it is therefore not necessary to install a Data Safety Monitoring Board (DSMB).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: infants aged 0 to 16 years of age with a primary unilateral inguinal hernia, undergoing hernia repair.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: Children with 1. incarcerated inguinal hernia, which have to be operated urgently, 2. recurrent hernia 3. ventricular-peritoneal drain, 4. non-descended testis, 5. parents who are not able to understand the nature or consequences of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	08-02-2024
Enrollment:	464
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2025
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	ID
CCMO	NL71765.029.20