Hernia Exploration oR Not In Infants Analysis (HERNIIA)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22121

Source
NTR

Brief title
HERNIIA

Health condition

Inguinal hernia, Hernia repair, Contralateral exploration, Metachronous contralateral inguinal hernia, Cost-effectiveness, Infants

Dutch: Liesbreuk, Liesbreukherstel, Contralaterale exploratie, Metachrone contralaterale liesbreuk, kosteneffectiviteit, zuigelingen

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Number of infants that undergo a second operation.

Secondary outcome

2. Total health care costs associated with each strategy.

3. Total number and duration of operation(s), anesthesia time and hospital admission(s).

4. Occurence of complications (wound infection, hematoma/hydrocele, testicular atrophy, apnea or recurrence) related to hernia repair.

5. Health-related quality of life (HRQOL) of the operated infants and their family.

Study description

Background summary

This study evaluates the effectiveness and cost-effectiveness of contralateral surgical exploration during unilateral inguinal hernia repair in children younger than six months with a unilateral inguinal hernia. In half of the participants contralateral exploration will be performed, while in the other half solely unilateral inguinal hernia repair will be performed.

Study objective

Contralateral exploration during unilateral inguinal hernia repair in children younger than six months reduces the incidence of
contralateral inguinal hernia and decreases the number and total duration of operations, anesthesia time and hospital admissions and is associated with reduced health-care costs, less complications and better quality of life compared to no exploration.

Study design

T1: Baseline

T2: Four weeks after primary hernia repair

T3: One year after primary hernia repair

Intervention

Contralateral exploration

Contacts

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Eligibility criteria

Inclusion criteria

Infants aged six months or younger with a primary unilateral inguinal hernia, undergoing open hernia repair

Exclusion criteria

- Children with 1. incarcerated inguinal hernia, who have to be operated urgently, 2. ventricular-peritoneal drain, 3. non-descended testis

- Patients who receive bilateral inguinal hernia repair because of increased operation risks (e.g. poor pulmonary condition)

- 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2019
Enrollment:	378
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	24-07-2018
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	NL7194
NTR-old	NTR7384
Other	852001903 : 2017.596

Study results