A randomized controlled trial to study the necessity and cost-effectiveness of contralateral surgical exploration during inguinal hernia repair in children. Hernia Exploration oR Not In Infants Analysis (HERNIIA).

Published: 03-07-2018
Last updated: 12-04-2024

To study the effectiveness and cost-effectiveness of contralateral exploration as compared to no contralateral exploration in children aged 6 months or less that undergo unilateral inguinal hernia repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON50346

Source
ToetsingOnline

Brief title
HERNIIA-trial

Condition

- Congenital and hereditary disorders NEC
- Therapeutic procedures and supportive care NEC

Synonym
groin rupture, Inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Contralateral hernia exploration, - Inguinal hernia repair, - Metachronous inguinal hernia, - Pediatric inguinal hernia

Outcome measures

Primary outcome

Number of operations related to inguinal hernia within one year after inguinal

hernia repair.

Secondary outcome

Length of hospital stay related to inguinal hernia; Complications of surgery

(testicular atrophy, wound infection, apnoea, recurrence); Total duration of

operations (including anaesthesia) related to inguinal hernia repair; Direct

and indirect costs related to inguinal hernia repair within one year after

surgery; Health-related Quality of Life of the operated infants and

parents/caretakers.

Study description

Background summary

There is a high incidence of metachronous (i.e. a second) contralateral inguinal hernia (MCIH) in infants with an inguinal hernia (5-30%, most studies report 10%), with the highest risk in infants aged less than 6 months. Metachronous hernia is associated with the risk of incarceration and general risks and costs of a second operation. This can potentially be avoided by

contralateral exploration at the first operation. On the other hand contralateral exploration may turn out to be unnecessary, is associated with additional operating time and cost, and may be associated with additional complications of surgery (including testicular atrophy, wound infection). Both policies to routinely explore the contralateral side or not are used in the treatment of unilateral inguinal hernias in children. There is no high-grade level of evidence of the superiority of one of either policy.

Study objective

To study the effectiveness and cost-effectiveness of contralateral exploration as compared to no contralateral exploration in children aged 6 months or less that undergo unilateral inguinal hernia repair.

Study design

A multicentre randomised controlled trial. Infants that need to undergo unilateral inguinal hernia repair will be randomised to either contralateral exploration or no contralateral exploration.

Intervention

Contralateral exploration or no contralateral exploration in chrildren with unilateral inguinal hernia repair.

Study burden and risks

Burden: contralateral exploration may turn out to be unnecessary, is associated with additional operating time and cost, and may be associated with additional complications of surgery. No contralateral exploration may lead to development of metachronous contralateral hernia with risk of incarceration, second anaesthesia and general risks and costs of a second operation.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants aged 6 months or younger
Primary unilateral inguinal hernia
Undergoing open hernia repair

Exclusion criteria

Incarcerated inguinal hernia in need for an emergency operation
Ventricular-peritoneal drain
Non-descended testis
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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2019
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2020
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	NL59817.029.18
Other	volgt nog