Effectiveness of total extraperitoneal hernia correction for clinically occult inguinal hernia: a multicenter randomized controlled trial

Published: 10-10-2017
Last updated: 19-03-2025

To evealuate the (cost-)effectiveness of endoscopic totally extraperitoneal (TEP) inguinal hernia correction comparecd to watchful waiting in patients with groin pain and a clinically occult inguinal hernia.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55469

Source
ToetsingOnline

Brief title
EFFECT trial

Condition

- Other condition

Synonym
groin hernia, Inguinal hernia

Health condition

Liesbreuken

Research involving

Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: zonMW

Intervention

Keyword: Cost-effectiveness, Inguinal hernia, Occult, TEP

Outcome measures

Primary outcome

The primary outcome measure of this study will be the reduction in pain intensity, measured in rest and during physical activity by the Numeric Rating Scale (NRS), 3 months after treatment.

Secondary outcome

Secondary outcome measures are: Pain intensity 1.5,6 and 12 months after treatment, quality of life, health care use, duration to resumption of daily and professional activities, positive predictive value of ultrasonography for detection of a clinically occult groin hernia, comparability outcomes of ultrasonography and MRI for detection of a clinically occult groin hernia, cross-over rate, patient satisfaction and cost-effectiveness.

Study description

Background summary

Groin pain is a frequent complaint in surgical practice, with an inguinal hernia being at the top of the differential diagnosis. Correction of an inguinal hernia is the most commonly performed elective surgical intervention worlwide with an estimated 30.000 procedures in the Netherlands annually. In the majority of cases an inguinal hernia is a clinical diagnosis based on the

classical presentation of a reducible groin swelling with a positive cough impulse sometimes accompanied with pain. However, patients presenting with groin pain without signs of an inguinal hernia provide a diagnostic challenge. Other frequently seen causes of groin pain are, for example, of myogenic, neurogenic or osseous origin. If ultrasonography, which most often is the first additional imaging modality to be ordered, shows an inguinal hernia that could not be diagnosed clinically, the radiological hernia is called a clinically occult groin hernia. In accordance with the current guidelines (European Hernia Society), radiologic presence of an inguinal hernia often leads to surgical intervention. However, in daily practice, correction of a clinically occult groin hernia often does not lead to pain relief. It is plausible that when a radiologic finding of an inguinal hernia is present, the hernia is not the actual cause of groin pain in all case, and another cause for the pain may exist. Hence, not all patients with a clinically occult hernia will benefit from surgical intervention. Until now, no clinical studies have been performing focussing on the effect of an inguinal hernia correctoin on the course of pain in patients with a clinically occult groin hernia.
Would this study demonstrate a watchful waiting approach is non-inferior to a TEP inguinal hernia correction, unnecessary surgery can be avoided, wich will lead to a higher health care efficiency and higher cost-effectiveness.

Study objective

To evealuate the (cost-)effectiveness of endoscopic totally extraperitoneal (TEP) inguinal hernia correction comparecd to watchful waiting in patients with groin pain and a clinically occult inguinal hernia.

Study design

The study design is a multicenter non-blinded randomized controlled non-inferiority trial.

Intervention

The intervention to be evaluated in this study is the endoscopic total extraperitoneal (TEP) inguinal hernia correction.

Study burden and risks

All the participants will undergo physical examination on their first visit to the outpatient clinic. If they decide to participate in the trial , they will be asked to fill out pre-operative questionnaires before start of treatment. They will be asked to fill out additional questionnaires the following moments: After 1.5, 3, 6 and 12 months from start of treatment. Three and 12 months after treatment additional visits to the outpatient clinic will be scheduled where they will undergo physical examination. There are no additional

risks related to this trial.

Contacts

Public
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582 KE
NL
Scientific
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582 KE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults (18 years or older)
Unilateral groin pain
No features of an inguinal hernia on physical examination
Inguinal hernia diagnosed on ultrasonography (on the side of the groin pain)

Exclusion criteria

Previous inguinal hernia on the symptomatic side
Previous surgery of the inguinal region at the symptomatic side
BMI 40 or higher
ASA classification above III

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:	Recruiting
Start date (anticipated):	30-01-2018
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-09-2018

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-08-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21825
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61730.100.17
OMON	NL-OMON21825