No registrations found.

**Ethical review**  Positive opinion  
**Status**  Pending  
**Health condition type**  -  
**Study type**  Interventional  

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**Summary**

**Source**
NTR  

**Brief title**
EFFECT trial  

**Health condition**
Inguinal hernia, clinically occult, TEP, pain, quality of life, cost-effectiveness  
Liesbreuk, klinisch occult, pijn, kwaliteit van leven, kosteneffectiviteit  

**Sponsors and support**
Primary sponsor : Hospital: Diakonessenhuis Utrecht/ Zeist, the Netherlands  
Source(s) of monetary or material Support : ZonMw  

**Intervention**

**Outcome measures**

**Primary outcome**
Reduction in pain intensity, measured in rest and during physical activity by the numeric rating scale (NRS)
Secondary outcome

- Pain intensity 1, 5, 6 and 12 months after treatment
- Quality of life
- Health care use
- Duration to resumption of daily and professional activities
- Morbidity after treatment
- Cross-over rate
- Patient satisfaction
- Cost-effectiveness

Study description

Background summary

Objective

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

Hypothesis

A watchful waiting approach is non-inferior to application of the endoscopic totally extraperitoneal (TEP) inguinal hernia correction in terms of pain reduction and quality of life 3 months after treatment.

Study design

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

Study population
The study population will consist of patients with groin pain and a clinically occult inguinal hernia; no features of an inguinal hernia can be detected on physical examination, while ultrasonography shows an inguinal hernia on the symptomatic side.

**Intervention**

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

**Comparison**

Outcomes of TEP inguinal hernia repair will be compared to a watchful waiting approach. Treatment will consist of rest, painkillers and optional physiotherapy.

**Outcome measures**

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 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, patient satisfaction and cost effectiveness.

**Sample size**

Based on the assumption that both treatments will be similar in terms of pain reduction 3 months after treatment, a sample size that could detect the smallest clinically relevant difference between the two treatment modalities was calculated. Using an equivalence margin of a NRS of 0.75, the total sample size should be at least 160 patients, with 80 patients per arm.

**Time schedule**

The study duration will be 42 months. The first period up to a maximum of 30 months will consist of inclusion and follow-up, in the period hereafter follow-up, data analysis and reporting of the results will be performed.

**Study objective**

A watchful waiting approach is non-inferior to application of the endoscopic totally extraperitoneal (TEP) inguinal hernia correction in terms of pain reduction and quality of life.
months after treatment

**Study design**

Baseline, 1.5 months after treatment, 3 months after treatment, 6 months after treatment, 12 months after treatment

**Intervention**

- Endoscopic totally extraperitoneal (TEP) inguinal hernia correction

- Watchful waiting approach (treatment will consist of rest, painkillers and optional physiotherapy)

**Contacts**

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**Eligibility criteria**

**Inclusion criteria**

- Age 18 years or older

- Unilateral groin pain (minimum NRS score of 1 during rest and/or physical activity)
- No features of an inguinal hernia on physical examination
- Radiologic diagnosis of an inguinal hernia on ultrasonography

**Exclusion criteria**

- Previous inguinal hernia on the symptomatic side
- Previous surgery in inguinal region of the symptomatic side
- BMI > 40
- ASA classification > III
- Reasons that complicate follow-up by means of questionnaires (eg. language barrier, psychiatric disorders)
- Unwilling to undergo surgery

**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: Pending
- Start date (anticipated): 29-12-2017
- Enrollment: 160
- Type: Anticipated
Ethics review

Positive opinion
Date: 13-11-2017
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

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Study results