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

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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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21825

Bron
NTR

Verkorte titel
EFFECT trial

Aandoening

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

Ondersteuning

Primaire sponsor: Hospital: Diakonessenhuis Utrecht/ Zeist, the Netherlands
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- Endoscopic totally extraperitoneal (TEP) inguinal hernia correction

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

Contactpersonen

Publiek

Coen Hessen, van
Bosboomstraat 1

Utrecht 3582 KE
The Netherlands
088-2505493

Wetenschappelijk

Coen Hessen, van
Bosboomstraat 1

Utrecht 3582 KE
The Netherlands
088-2505493

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	29-12-2017
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55469
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6658
NTR-old	NTR6835
CCMO	NL61730.100.17
OMON	NL-OMON55469

Resultaten