'Validation of the EuraHS-quality of life questionnaire for patients with ventral abdominal wall hernia'

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The EuraHS-QoL questionnaire is a valid instrument to measure quality-of-life before and after ventral hernia repair.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22582

Bron
NTR

Verkorte titel
CAMEL-study

Aandoening

Abdominal wall hernia, umbilical hernia, epigatric hernia, incisional hernia, ventral hernia.

buikwandbreuk, buikwandhernia, littekenbreuk, ventrale hernia, navelbreuk.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary objective: The aim of this study is to evaluate the validity and reliability of a novel ventral hernia quality of life score (EuraHS-QoL) to assess pain, restrictions and cosmetic discomfort of patients with ventral hernias before and after reconstructive surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

1. SUMMARY

Rationale: Ventral hernias are frequently encountered in the surgical outpatient clinic. Many techniques have been described to repair both incisional and primairy ventral hernias, though very few studies have evaluated the outcome in terms of quality of life following these surgical interventions. In part, this can be attributed to the absence of a proper investigational tool. Several quality of life questionnaires have been validated for ventral hernias, though non of them can be used both pre- and postoperatively and combine both esthetical appearance of the abdomen and function outcome. The EuraHS-QoL questionnaire is a unique tool especially developed to measure quality of life in hernia patients.

Objective: Validation of the EuraHS-QoL by evaluating specificity and statistical validity

Study design: Prospective cohort study with questionnaire inquiries

Methods: All patients will be asked to fill out the RAND-36 (Based on SF-36) quality of life (QoL) questionnaire and the European registry of abdominal wall hernias quality-of-life (EuraHS-QoL) questionnaire preoperative and the EuraHS-QoL and Caroline Comfort Scale (CCS) postoperatively. Once after 2-4 weeks and twice after one year follow-up with an interval of 2 weeks.

Study population: 170 patients with ventral hernia scheduled for surgical repair that will complete the test-retest measurement at one year follow up and 60 healthy volunteers.

Study Duration: the study will end when 170 patient have completed the test-retest measurement after 1 year post-op

Doel van het onderzoek

The EuraHS-QoL questionnaire is a valid instrument to measure quality-of-life before and after ventral hernia repair.

Onderzoeksopzet

- before the operation (RAND-36, EuraHS-QoL) questionnaire

- 2-4 weeks after the surgery (EuraHS-QoL CCS)

- 12 months after surgery (CCS, EuraHS-QoL).and again two weeks later both questionnaires at home.

Onderzoeksproduct en/of interventie

none

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age between 18 and 80 years

- Able to read and understand the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- - any patient that is considered unable to provide a reliable answer to the questionnaire (example: severe dementia, mental retardation, language barrier etc).

- - Patients with a life expectancy less than 24 months

- - Patients with chronic steroid dependency

- - Patients with rectus diastasis (without additional ventral hernia)

- - Patients with parastomal hernia(s)

- - Pregnant women

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016

Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5349
NTR-old	NTR5582
Ander register	METC : 2015-76

Resultaten

Samenvatting resultaten

none