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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22582

Source
NTR

Brief title
CAMEL-study

Health condition

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

buikwandbreuk, buikwandhernia, littekenbreuk, ventrale hernia, navelbreuk.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary objectives: Assessment of the QoL preoperative, 2-4 weeks, and twice at 1 year postoperative, recurrence rate at 12 months, intra-operative and post-operative complications, post-operative hospital stay, operation time and time to place the mesh, VRS (Verbal Rating Score) for pain at 2-4 weeks and 12 months, pain medication as needed.

Study description

Background summary

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

Study objective

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

Study design

- 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.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 80 years

- Able to read and understand the Dutch language

Exclusion criteria

- - 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016

Enrollment:	170
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL5349
NTR-old	NTR5582
Other	METC : 2015-76

Study results

Summary results
none