

Long-term follow-up of complex abdominal wall repair

Published: 31-08-2016

Last updated: 17-04-2024

1. To investigate short- as well as long-term outcomes in patients who underwent CAWR in the Academic Medical Center and St Marks Hospital London between 2004 and 2015 with hernia recurrence as primary outcome. Secondary outcomes involve morbidity,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Observational non invasive

Summary

ID

NL-OMON43039

Source

ToetsingOnline

Brief title

AWARE study

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym

abdominal wall hernia, hernia

Research involving

Human

Sponsors and support

Primary sponsor: AMC, afdeling chirurgie

Source(s) of monetary or material Support: investigator-initiated op basis van diverse bronnen (uit budget van gerelateerd onderzoek van Prof. dr. Boermeester). Dit is enkel voor reiskosten vergoeding patiënt (zie G3a)

Intervention

Keyword: Abdominal, Complex, Follow-up, Pre-operative CT-scan, Wall

Outcome measures

Primary outcome

Hernia recurrence

Secondary outcome

1. Short-term: Post-operative wound complications, intra-abdominal complications, medical complications, length of hospital stay, re-operations, emergency department visits, re-admissions and short-term mortality.
2. Long-term: Bulging, hernia recurrence, occurrence of a parastomal hernia, fistula formation (recurrence), re-operation for recurrence, scar assessment, patient satisfaction and long-term mortality.

Study description

Background summary

Patients undergoing major complex abdominal wall repair (CAWR) are at high risk to develop (wound) complications. Long-term results are not well known as most studies investigate only the short-term results. Moreover, the role of pre-operative CT-scanning in complex abdominal wall repairs is becoming more important. The exact role of CT findings in surgery preparation is not known.

Study objective

1. To investigate short- as well as long-term outcomes in patients who underwent CAWR in the Academic Medical Center and St Marks Hospital London between 2004 and 2015 with hernia recurrence as primary outcome. Secondary outcomes involve morbidity, mortality and patient related outcomes.
2. To investigate whether CT derived measurements help to predict what complex abdominal wall reconstructive techniques are required to repair a given defect and predict outcome.

Study design

Data on patient characteristics, CT-scan characteristics, operation details and postoperative data were assessed as retrospective cohort study. Hernia recurrence on the long-term was measured at one prospective follow-up moment.

Study burden and risks

The risks associated with participating in this study are negligible. We ask patients* time to visit the outpatient clinic of the AMC once. This consultation will take approximately 20-30 minutes and involves a short physical examination, filling out a questionnaire, and taking two photographs of the abdominal wall.

Contacts

Public

Selecteer

Meibergdreef 9 G4-132.1
Amsterdam 1105AZ
NL

Scientific

Selecteer

Meibergdreef 9 G4-132.1
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Complex abdominal wall repair in Academic Medical Center Amsterdam or St Marks Hospital London between 2004-2015
- Midline incision
- VHWG grade 3 of 4, modified VHWG grade 3

Exclusion criteria

- < 19 years old
- emergency procedure
- parastomal, lumbar, lateral and subcostal hernia
- multiple staged procedure
- patients undergoing enterocutaneous fistula repair without concomitant abdominal wall defect reconstruction

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 03-10-2016

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 31-08-2016

Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL56765.018.16