

Safer & More Efficient Closure of Trocar Wounds; Manual vs. Automated, a Pilot Trial

Published: 28-08-2019

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Primary objectivesTime needed for proper closure of the trocar wounds with the automated deviceSecondary objectivesDemonstrate user-friendliness of the Medfclose System

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON52564

Source

ToetsingOnline

Brief title

ATC

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym

Trocar wounds

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: bedrijf,Health Value creation

Intervention

Keyword: Automated trocar closure, Laparoscopic surgery, Manual Closure, Trocar Wounds

Outcome measures

Primary outcome

Time needed to close the trocar wounds with the automated device .

Secondary outcome

Self-reported easiness for the surgeons to close trocar wounds

Study description

Background summary

Laparoscopy is becoming the preferred method of surgery due to its enhanced recovery following urological, gynecologic and surgical procedure. Access to the abdomen for surgery is done by inserting trocars through the abdominal wall as work ports. Adequate closure of these trocar wounds is done by sutures running through the strong abdominal fascia surrounding the muscles. This remains a challenge, especially in obese patients. Surgical hernia*s following trocar wounds are found in 2-10% of cases.To circumvent these postoperative problems Corporis Medical designed the MEDICLOSE system, to automatically close these trocar wounds safely.

Study objective

Primary objectives

Time needed for proper closure of the trocar wounds with the automated device

Secondary objectives

Demonstrate user-friendliness of the Mediclose System

Study design

Pilot trial: the trocar wounds will be closed with the automated closure device. Following closure the wound will be checked for adequate closure by palpating with the finger. Time for closure of the wounds will be registered, additionally the operating surgeon will be asked to score the easiness of closure the wounds.

Intervention

After proper inclusion, the trocar wound is closed with the automated device incorporating a suture identical to Vicryl suture thickness *0*. Following the closure, the wound is palpated for adequate closure by the surgeon and subsequently reported. Time to closure of the wounds is reported for both techniques. Patients will receive standard post-operative care as described in hospital protocol.

Study burden and risks

No substantial risk or burden is anticipated for patients participating in this study. The developed device is operated under camera control. The sutures used are standard Vicryl sutures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Oral and written informed consent (IC)

Age 18 years and older

Elective surgery

Exclusion criteria

No informed consent

Palliative surgery

Emergency surgery

Mental handicap

Pregnancy

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-04-2021

Enrollment: 40

Type: Actual

Medical products/devices used

Generic name: Mediclose system (Automatic Trocar Closure (ATC) device)

Registration: No

Ethics review

Approved WMO

Date: 28-08-2019

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL67234.068.18
Other	NL7636