

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

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automatic closure of 10-12mm trocar wounds is faster and more efficient compared to manual suturing

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

Samenvatting

ID

NL-OMON21562

Bron

NTR

Verkorte titel

Mediclose

Aandoening

not applicable

Ondersteuning

Primaire sponsor: MUMC

Overige ondersteuning: Funded by investing partners

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to closure of trocar wounds

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Rationale

Laparoscopy is becoming the preferred method of surgery due to its enhanced recovery following urological, gynecologic and surgical procedure. For surgery, access to the abdomen is done by inserting trocars as work ports, through the abdominal wall. Adequate closure of these trocar wounds is done by running sutures 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%¹ of cases. The Medclose system has been designed to prevent herniation. The innovative mechanism of the Medclose system places the fascia directly into the path of the needles, by reshaping the trocar wound into an ellipse. After the Medclose system fires the needles, the suture is passed through the fascia, enabling wound closure.

Patients and Study Design

Patients undergoing laparoscopic surgery in the described participating hospitals, necessitating at least 1 trocars (not with open introduction) size 10-12mm will be asked to participate in this trial. Patients must be 18 years and older. Informed consent must be obtained from all patients. Patients undergoing palliative treatment or emergency surgery will be excluded from this study.

In total 40 patients will be included in the PILOT trial and the trocar wounds will be closed by the Medclose system. 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

Data analyses

Data will be coded and prospectively collected and entered into a protected online database through eCRF's. Data management is performed via an independent agency.

Study Endpoints

Primary objectives

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

Secondary objectives

1. Demonstrate user-friendliness of the Medclose System

Evaluation

Analysis of use of the Medclose System and satisfaction with the device from professional perspective, including well-being of patient.

Doel van het onderzoek

automatic closure of 10-12mm trocar wounds is faster and more efficient compared to manual suturing

Onderzoeksopzet

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Contactpersonen

Publiek

Antoni van Leeuwenhoek ziekenhuis
Alexander Veenhof

0205129111

Wetenschappelijk

Antoni van Leeuwenhoek ziekenhuis
Alexander Veenhof

0205129111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Oral and written informed consent (IC)
Age 18 years and older
Elective laparoscopic surgery with at least one 10-12 mm trocar used

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No informed consent
Palliative surgery
Emergency surgery
Mental handicap

Women which are pregnant
Women which are breastfeeding

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	02-04-2019
Soort:	Eerste indiening

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	NL7636
Ander register	METC MUMC : METC18-055

Resultaten