The turbine-based insufflator: a clinical safety and feasibility study during laparoscopy

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56486

Source
ToetsingOnline

Brief title
Turbine-based insufflator

Condition

- Other condition

Synonym
Minimal access surgery for intra-abdominal pathology

Health condition

geen specifieke aandoening, heeft betrekking op abdominale laparoscopische procedures

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Health~Holland (topsector Life Sciences and Health),Spatium Medical B.V.

Intervention

Keyword: Abdominal compliance, Endoscopic oscillometry, Insufflation pressure, Laparoscopy

Outcome measures

Primary outcome

The number and nature of (serious) adverse device effects related to the

turbine-based insufflator that occur during use.

Secondary outcome

- Determination of pressure stability throughout all procedures.

- Identification of events that impair insufflation pressure stability.

- Determination of the gas volume exchange required to keep insufflation

pressures stable, absolute and in relation to ventilation tidal volumes.

- Investigation of ventilator action and insufflator response in terms of

amplitude and temporal offset.

- Comparison between the insufflation pressure chosen by the surgeon and the

optimal pressure derived from endoscopic oscillometry.

- Evaluation of the applied pressure amplitudes and frequencies needed basing

on patient*s weight and size, in order to get reference values of the abdominal

cavity*s compliance [L/hPa] in humans.

- Evaluation of flows generated by the oscillation pressures applied for the

purpose of sizing measuring instruments (flowmeters).

- Evaluation of the range of frequencies used in oscillometry on patients* size and weight for estimating the compliance.

- Comparison of pressure and flow time tracing both in ventilation and insufflation to derive the static compliance of the respiratory system.

- Compensation of ventilation effects on pressure and flow signals. A post-processing analysis of the acquired signals will be done in order to filter out these effects and retain the information on the applied forced oscillations.

- Optimization of endoscopic oscillometry in patients with different breathing rates.

Study description

Background summary

Surgical workspace in minimal access surgery is created using an insufflation device that pressurizes CO2 gas. The principle behind these devices has remained unchanged for decades, and depends on the creation of a static pressurized gas volume that is strongly affected by external pressures, and vice versa exerts pressure onto the surrounding structures. As a consequence, organ perfusion and venous return are reduced, high ventilation pressures are required to compensate for the insufflation pressure and patients often report postoperative pain following insufflation. Erasmus MC and Politecnico di Milano have developed a new insufflator based on turbine technology, which allows very stable pressures by allowing insufflation gas flow between the abdominal cavity and a reservoir within the insufflator.

This first in-human-trial has the primary aim of evaluating safety and feasibility of turbine-based insufflation in adults undergoing laparoscopic surgery.

Study objective

The primary objective of this study is to determine the safety and feasibility of turbine-based insufflation, measured in terms of occurrence of adverse

device effects and serious adverse device effects. The secondary objectives are to determine the pressure stability performance during the procedures, as well as the ability to measure abdominal compliance using endoscopic oscillometry during initial insufflation.

Study design

This study is a prospective clinical safety and feasibility trial of the turbine-based insufflator in intraperitoneal laparoscopy. In total, 12 patients will be included and are planned for laparoscopy. At the start of each procedure, oscillometric measurements will be done during initial insufflation of the abdomen, after which the procedure will be performed at the insufflation pressure chosen by the surgeon. The insufflator is monitored throughout the procedure and checked for safety and feasibility. Any device-related events are recorded. Besides, the conventional insufflator will be standby if needed.

Study burden and risks

Apart from containing informed consent prior to the study no additional contact moments have been scheduled for the subject.

During surgery, the surgeon will use the turbine-based insufflator instead of the conventional insufflator. At the beginning of surgery, the insufflation pressure will be gradually increased, prolonging the operation with a few minutes. No additional risks are expected, because of the minimum duration of extra time needed.

Previous research in animals and in vitro models has shown no adverse device effects. The risk of (S)ADEs is therefore estimated as low. The device complies with technical standards, which limits the consequences of malfunctions. If the device exceeds the threshold values, for example of pressure and temperature, an alarm will warn the surgeon. Rapid action can be taken and, if necessary, the surgeon can switch to a conventional insufflator that will be on standby at all times during the surgical procedure, so that the procedure can be resumed as fast as possible.

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

- Adults (>=18 years old)
- Elective surgery
- Intraperitoneal laparoscopy
- Planned use of a main 12 mm trocar

Exclusion criteria

- Inability to contain the insufflation gas to the intraperitoneal space
- Pregnancy

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-04-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Turbine-based insufflator
Registration:	No

Ethics review

Approved WMO Date:	13-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85402.078.23