Driving pressure during general anesthesia for open abdominal surgery - a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON55943

Source
ToetsingOnline

Brief title
DESIGNATION

Condition

- Respiratory disorders NEC

Synonym
Postoperative pulmonary complications

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Driving pressure, Mechanical ventilation, Positive end expiratory pressure (PEEP), Pulmonary Complications

Outcome measures

Primary outcome

The primary outcome measure is a composite of PPCs in the first 5 postoperative

days.

Secondary outcome

• Intraoperative fluid strategy

• Intraoperative complications including:

- Desaturations

- Hypotensions

- Need for vasoactive medications

- New arrhythmias needing intervention

• Impaired wound healing

• Postoperative extrapulmonary complications

• All-cause mortality at day 5, day 90 and day 90

• Unplanned admission to an intensive care and length of stay in Intensive care

unit

• Length of hospital stay.

Study description

Background summary

Postoperative pulmonary complications (PPCs) develop frequently in patients

undergoing major surgery. PPCs are strongly associated with a longer hospital stay and mortality. Use of a 'lung protective' intraoperative ventilation strategy prevents against PPC's, though there is debate on which ventilator setting is most effective. Intraoperative driving pressure is strongly associated with the development of PPCs.

Study objective

The overall objective of this RCT is to determine the effectiveness and long-term outcome of an high PEEP strategy, aiming at preventing atelectasis, but avoiding an increase in driving pressure, during intraoperative ventilation. Specifically, this will be a superiority trial comparing individualized high positive end expiratory pressure (PEEP) with standard low PEEP in patients at increased risk of developing PPC's.

Study design

International multicenter double blinded randomized controlled trial

Intervention

An individualized high PEEP, aiming at avoiding an increase in the driving pressure will be compared to a standard low PEEP during intraoperative ventilation.

Study burden and risks

During surgery, the patient is under general anesthesia and will therefore not notice the use of lung-protective ventilation. There is little extra risk for the patient. However, when using higher airway pressures it can be necessary to administer extra fluid in the circulation or medication to increase the blood pressure. Patients in the intervention group could benefit from lung-protective ventilation, which potentially decreases their risk of development of PPCs.

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

Increased (i.e., intermediate or high) risk of postoperative pulmonary complications (according to the ARISCAT risk score [>= 26] , Scheduled for open abdominal surgery in one of the participating centers

Exclusion criteria

Planned for laparoscopic surgery;
Planned for surgery in prone or lateral position;
Planned combined procedure with open abdominal and intrathoracic surgery;
Age < 18 years;
Body mass index > 40 kg/m2;
Reported pregnancy;
Having received mechanical ventilation for longer than 30 minutes (e.g., because of general anesthesia for surgery) within last 30 days;
Any major previous lung surgery;
History of previous severe chronic obstructive pulmonary disease (COPD) GOLD III or IV, or with (noninvasive) ventilation and/or oxygen therapy at home;
(previous) acute respiratory distress syndrome (ARDS);
Expected to require postoperative mechanical ventilation;
Persistent hemodynamic instability or intractable shock;
Severe cardiac disease (New York Heart Association class III or IV, or acute coronary syndrome, or persistent ventricular tachyarrhythmia*s);
Consent for another interventional study in anesthesiology; or

No written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2019
Enrollment:	1250
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
ClinicalTrials.gov	NCT03884543
CCMO	NL67684.018.18