Investigation of the safety of ventilation with Ventrain in patients during a planned operation

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Demonstrate the safety and efficacy of ventilation with Ventrain® during 5 minutes. Safety is demonstrated if the peak pressure during insufflation does not exceed 25 cm H2O and PEEP (Positive End Expiratory Pressure) is not smaller than -5 cm H2O...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON40890

Source
ToetsingOnline

Brief title
Ventrain

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Study of the safety of ventilation through a narrow tube during operation

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Zelf vanuit vakgroepen

Intervention

Keyword: Reanimation, Ventilation, Ventrain

Outcome measures

Primary outcome

- Demonstrate the safety and efficacy of ventilation with Ventrain® during 5 minutes. Safety is demonstrated if the peak pressure during insufflation does not exceed 25 mm H2O and PEEP is not smaller than -5 mm H2O and not higher than 6 mm H2O. The number of interventions from the safety-person dr. C will be the primary endpoint. We assume that the interventionrate will be less than 15%.

Powercalculation

As this can be seen as a pilot study and no information is available at this moment.

However. the primary outcome is the number of interventions from the safety-person dr. C . We assume that this will be less than 15%. With 20 patients we can exclude the possibility that this failure proportion is higher than 13.9%. One sided tested the CI will be less than 13.9%.

Secondary outcome

Measure the different parameters during ventilation with the Ventrain® as there are lung pressure, peak lung pressure, PEEP, capno, oxygen saturation, tension and heart rhythm.

Study description

Background summary

Ventrain® is the first ventilation device that provides adequate ventilation through a narrow-bore catheter, even in case of a completely obstructed upper airway. Ventrain®, a product specifically designed for *cannot intubate, cannot ventilate* emergencies, makes airway management in such life-threatening situations easier and safer. With Ventrain, we have full ventilation through only a 2 mm catheter.
Ventrain® not only insufflates oxygen, but also provides active removal of gas from the lungs: expiratory ventilation assistance, or in short EVA.
EVA shortens the expiration time, increases the achievable minute volume and prevents air trapping. Therefore, Ventrain® considerably reduces the chance of intrapulmonary pressure build-up and the associated risks of barotrauma and circulatory collapse. Active expiration is created by the special design that optimizes a
balance between the Venturi effect and jet entrainment.
Ventrain® has been used in several cases of emergency of which several cases have been published (ref). It has even been used in two life-saving airway emergencies in neonates (ref).
These publications have been single cases. Despite several tests in animals and lung simulators, there are still some worries for high pressures during ventilation. In the present study we would like to demonstrate the safety of ventilation (during 5 minutes) with Ventrain® in a series of patients prepared for an operation. During reanimations generally no pressure or other measurements are performed. During these controlled and well planned ventilations these measurements can be performed.

Study objective

Demonstrate the safety and efficacy of ventilation with Ventrain® during 5 minutes. Safety is demonstrated if the peak pressure during insufflation does not exceed 25 cm H2O and PEEP (Positive End Expiratory Pressure) is not smaller than -5 cm H2O and not higher than 6 cm H2O.

Study design

1. Patients are approached to participate in the study during the pre-operative period by the anaesthesist.
2. Patients will have at least 1 week to think about the study and will then be approached for their answer.
3. Patients willing to be included will be planned for an OR at a time that the study can be performed.
4. For the OR an additional +- 15 minutes will be scheduled.
5. All patients will be intubated as usual with a tube of 7-8 mm. The tube is prepared on the OR with an airway exchange catheter Cook 3 mm and with a line for pressure measurements. The insertion of these materials will be facilitated

by wetting the materials with sterile water.
6. The prepared tube will be brought into the patient.
7. From the moment that the ventilation of the patient starts two persons will be available for the ventilation. The first person (named dr B, as he will be blind for the pressure measurements) will perform the ventilation with the Ventrain. Dr B will only look at the patient and its chest.
8. The second person (dr C will control the pressures and makes sure that the patient never gets the boundaries of the pressures as stated earlier in the protocol. Dr C has the right and is obliged to finish the experiment at the moment the pressure boundaries are reached.
9. Dr B will use the Ventrain® as stated in the instructions for use, which means that after 5 ventilation cycles the Ventrain® is opened until the chest is in rest.
10 As a small tidal volume is preferred, the ratio of inspiration and expiration will be 1:1, which means 1 second inspiration and 1 second expiration.
11. The flow of the 100% oxygen will be set at 15 L/min.
12. The ventilation will be performed with the Ventrain® during 5 minutes.
13. After 5 minutes the Cook catheter and line for pressure measurements will be withdrawn from the tube. The 7-8 mm tube stays in situ during the following OR period.
14. The ventilation of the patient will be continued as normal.
15. Several measurement will be continued during the first 5 minutes of ventilation, such as oxygen saturation, heart rhythm and tension.
16. The OR will continue as usual. The experiment has ended.

Study burden and risks

The risk can be compared with the risk around normal operation procedures and each ventilation procedure.
The safety is guaranteed as a second person is taking care for the monitors and he/she will intervene if necessary.
The burden for the patient will be limited to a prolonged narcosis of maximal 15 minutes. We assume it will be around 5 minutes.

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

- ASA 1-2
- Planned for operation from orthopaedic, gynaecology or ENT
- Aged above 18 years and under 65

Exclusion criteria

- ASA more than 2
- Aged under 18
- Aged above 65
- Respiratory disease
- Cardiovascular disease
- Smokers
- Obese patients
- Pregnancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Ventrain
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-08-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL50090.096.14