

A Randomized Clinical Trial of the Effectiveness of Ventilation by Oxylator EMX versus Bag-Valve Device in pre-hospital emergency patients.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23375

Source

NTR

Brief title

Oxylator, respiratory failure, bag-valve device, prehospital

Health condition

All emergency conditions that require mask ventilation.

Sponsors and support

Primary sponsor: CPR Medical, Toronto Canada, www.cprmedic.com

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

1. Periferal oxygen saturation;

2. End tidal carbon dioxide (CO₂).

Secondary outcome

1. Survival to hospital;
2. Hospital O₂ saturation & ETCO₂;
3. Hospital Bloodgas.

Study description

Background summary

This randomised clinical trial compares the efficacy of a handheld pressure regulated ventilator (Oxylator EMX) to the bag-valve device on prehospital EMS patients that require mask ventilation.

Study objective

The Oxylator EMX is as effective as the Bag-Valve device in ventilating prehospital patients (bloodoxygen saturation and carbon dioxide).

Study design

N/A

Intervention

1. Mask ventilation with Oxylator EMX or Bag-valve device;
2. Measuring periferal saturation and end-tidal CO₂ with device.

Contacts

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Eligibility criteria

Inclusion criteria

EMS patients age > 18y requiring mask ventilation.

Exclusion criteria

1. Cardiac arrest;
2. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Suspended
Start date (anticipated): 02-05-2005
Enrollment: 200
Type: Anticipated

Ethics review

Positive opinion
Date: 08-09-2005
Application type: First submission

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
NTR-new	NL231
NTR-old	NTR268
Other	: 0515
ISRCTN	ISRCTN20664878

Study results

Summary results

N/A