

A randomised clinical trial of the effectiveness of ventilation by Oxylator® EMX versus bag-valve device in pre-hospital emergency patients

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 03/07/2009	Condition category Respiratory	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR268; 0515

Study information

Scientific Title

Study objectives

The Oxylator® EMX is as effective as the bag-valve device in ventilating pre-hospital patients (blood oxygen saturation and carbon dioxide).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, single-blind, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mechanical ventilation need

Interventions

1. Mask ventilation with Oxylator® EMX or Bag-valve device
2. Measuring peripheral saturation and end-tidal CO₂ (ETCO₂) with device

Intervention Type

Device

Phase

Not Specified

Primary outcome(s)

1. Peripheral oxygen saturation
2. End tidal carbon dioxide (CO₂)

Key secondary outcome(s)

1. Survival to hospital
2. Hospital O₂ saturation and ETCO₂
3. Hospital blood gas

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

Emergency Medical Services (EMS) patients aged greater than 18 years requiring mask ventilation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Cardiac arrest
2. Pregnancy

Date of first enrolment

02/05/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

St. Elisabeth Hospital

Tilburg

Netherlands

5000 LC

Sponsor information

Organisation

CPR Medical Devices Inc. (Canada)

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration