

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NTR268; 0515

# Study information

## Scientific Title

## Study objectives

The Oxlator® 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

## Study design

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

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Mechanical ventilation need

## Interventions

1. Mask ventilation with Oxlator® EMX or Bag-valve device
2. Measuring periferal saturation and end-tidal CO<sub>2</sub> (ETCO<sub>2</sub>) with device

## Intervention Type

Device

## Phase

Not Specified

## Primary outcome measure

1. Periferal oxygen saturation
2. End tidal carbon dioxide (CO<sub>2</sub>)

## Secondary outcome measures

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

**Overall study start date**

02/05/2005

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200

**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)

### **Sponsor details**

20 Summerhill Gardens  
Toronto, Ontario  
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### **Sponsor type**

Industry

## **Funder(s)**

### **Funder type**

Not defined

### **Funder Name**

Not provided at time of registration

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration