ISRCTN20664878 https://doi.org/10.1186/ISRCTN20664878

# 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

**Registration date**
20/12/2005

**Overall study status**
Completed

**Last Edited**
03/07/2009

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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**
Dr B. Drinkwaard

**Contact details**
St. Elisabeth Hospital
P.O. Box 90151
Tilburg
Netherlands
5000 LC

## 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

### Study design
Randomised, single-blind, active controlled, parallel group trial

### Primary study design
Interventional

### 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 periferal saturation and end-tidal CO2 (ETCO2) with device

### Intervention Type
Device

### Phase
Not Specified

### Primary outcome(s)
1. Periferal 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