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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 03/07/2009	**Condition category** Respiratory	

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 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

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

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
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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