ISRCTN47620321 https://doi.org/10.1186/ISRCTN47620321

Pre-hospital use of non-invasive ventilation improves acute respiratory failure

Submission date 26/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/05/2009	**Overall study status** Completed	
Last Edited 26/10/2011	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Willi Schmidbauer

Contact details
Scharnhorststraße 13
Berlin
Germany
10115
+49 (0)89 2841 2053
willi-schmidbauer@web.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03 K4-S-170607

Study information

Scientific Title
Pre-hospital use of non-invasive ventilation improves acute respiratory failure: a randomised controlled trial

Study objectives
Non-invasive ventilation (NIV) is used as ventilatory support without endotracheal intubation to spontaneously breathing patients and has been demonstrated to be feasible during hospital treatment of several forms of acute respiratory failure.

The aim of this study is to determine whether the early pre-hospital use of an emergency ventilator, enabling application of continuous positive airway pressure (CPAP) or non-invasive positive pressure ventilation (NIPPV) - according to clinical demand - is practicable and will improve dyspnoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charite - University Medicine Berlin gave approval (ref: EA1/140/06)

Study design
Prospective randomised pilot study

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
Acute respiratory failure

Interventions
Patients were assigned to one of two groups by closed envelope randomisation:
1. NIV (intervention group)
2. Standard oxygen therapy via face mask (control group)

In both groups, basic therapy included fenoterol, reproterol, terbutaline, prednisolone, theophylline, furosemide, nitroglycerin, and morphine according to clinical necessity and local standard operating procedures. Pre-hospital monitoring consisted of non-invasive arterial blood pressure, continuous pulse oxymetry, continuous electrocardiography (ECG), and 12-channel ECG.

The dyspnoea score measures the dyspnoea as declared by the patient with a range from 1 (no dyspnoea) to 10 (worst dyspnoea with the feeling of asphyxiation).

In addition to the above mentioned drug treatment, patients of the NIV group were initially supplied with CPAP of 5 cm H2O and an inspiratory oxygen fraction (FiO2) of 0.5 (Oxylog® 3000, Draeger Medical, Germany). NIV was applied via face mask, as this has been shown to be favourable compared to nasal masks. Goals of NIV therapy were improvement of dyspnoea score, reduction of respiratory rate less than 25/min, increase of SpO2 greater than 90%, decrease of and acceptance by the patients. In case of failure to reach these treatment goals, CPAP was increased primarily to 7.5 cm H2O and secondarily to 10 cm H2O. Next step of escalation was an additional application of pressure support of 5 cm H2O in the NIPPV modus. If necessary, pressure support was increased by steps of 5 cm H2O up to a peak inspiratory pressure (CPAP + pressure support) of 30 cm H2O. Last step of escalation of NIV treatment was an increase of FiO2 to 1.0. In case of failing the above mentioned goals or intolerance by the patient, NIV treatment was stopped and patient was excluded.

Patients of the control group were supplied by oxygen inhalation via face mask up to 12 l/min. In both groups endotracheal intubation was performed according physicians decision.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fenoterol, reproterol, terbutaline, prednisolone, theophylline, furosemide, nitroglycerin, morphine

Primary outcome measure
Rate of endotracheal intubation during first 24 hours of treatment.

Secondary outcome measures
1. Difference of baseline and admission values of:
1.1. Pulse oxymetric oxygen saturation
1.2. Respiratory rate
1.3. Dyspnoea score
1.4. Heart rate
1.5. Systolic diastolic arterial blood pressure
2. Duration of intensive care
3. Incidence and duration of mechanical ventilation, and hospital days
4. Feasibility of NIV was rated at a scale from 1 to 5 (very good, good, acceptable, difficult, not feasible)

Overall study start date
01/04/2007

Completion date
01/10/2008

Eligibility

Key inclusion criteria
Pre-hospital patients:
1. Aged above 18 years, either sex
2. Acute dyspnoea
3. Respiratory rate greater than 25/min
4. Pulse oxymetric oxygen saturation less than 90%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients

Key exclusion criteria
1. Refusal of NIV
2. Vomiting
3. Glasgow Coma Scale less than 12 points
4. Suspected myocardial ischaemia
5. Systolic blood pressure less than 100 mmHg
6. Pregnancy
7. Injury of face or neck
8. Participation in another study

Date of first enrolment
01/04/2007

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Germany

Study participating centre
Scharnhorststraße 13
Berlin
Germany
10115

Sponsor information

Organisation
Medical Service of the Bundeswehr (Sanitätsamt der Bundeswehr [SanABw]) (Germany)

Sponsor details
Dachauerstraße 128
Munich
Germany
80637
+49 (0)89 1249 7950
SanABw@bwb.org

Sponsor type
Government

Website
http://www.sanitaetsdienst-bundeswehr.de

ROR
https://ror.org/04y9zrf69

Funder(s)

Funder type
Government

Funder Name
Medical Service of the Bundeswehr (Sanitätsamt der Bundeswehr [SanABw]) (Germany) (ref: 03 K4-S-170607)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No