The 3CPO Study

ISRCTN: 07448447

Study number: | | | | | | Form number: | | | | |

3CPO: – MAIN DATA COLLECTION FORM

Before completing this form, please ensure you have filled in the study number above, and copied the form number (top right) onto the patient recruitment form.

Please complete ALL details on this page and page two and as much as you can on pages three and four. The Research Nurse will complete the rest of the form.

Section A: Intervention details

1. Which intervention was started?

Please tick one only – if more than one treatment was started, please tick the first treatment started and provide details of further interventions in Q4.

1. Standard treatment ○
2. NIPPV ○
3. CPAP ○

2. Treatment start time: __ __ : __ __ Treatment finish time: __ __ : __ __

3. What was the final level for:

(i.e. highest level of tolerance within 2 hours)

CPAP: ____________ cmH_2O

NIPPV: ____ / ____ cmH_2O

4. Was the allocated treatment completed? Yes ○ No ○

If not, why not?

- Patient did not tolerate treatment ○
- Worsening blood gases ○
- Increasing respiratory distress ○
- Other, please specify ○

____

5. If more than one intervention was started, please state which treatment was started after failure of intervention above.

- Standard treatment ○
- CPAP ○
- NIPPV ○
- Intubation ○
- Other (please specify) ○

____

PLEASE COMPLETE ALL PAPERWORK AND CONTINUE WITH 1 & 2 HOUR OBSERVATIONS EVEN IF PATIENT DOES NOT CONTINUE RANDOMISED TREATMENT

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Section A: Symptoms prior to admission

Has the patient had symptoms suggestive of MI during 12 hours before hospital attendance? Yes ◯ No ◯

Section B: Your observations

	Baseline (on considering eligibility)	One hour (after randomisation)	Two hours (after randomisation)
i. Pulse rate	______	______	______
ii. Blood pressure	______	______	______
iii. Respiratory rate	______	______	______
iv. Oxygen saturation (%)	______	______	______
v. Inspired O_2 concentration (O_2 l /min)	______	______	______
vi. Arterial pH	______	______	
vii. Arterial pO_2 (KPa)	______	______	
viii. Arterial pCO_2 (KPa)	______	______	
ix. Standard bicarbonate (mmol/l)	______	______	
x. Breathlessness score (0–10). Patient assessed – ask the patient	______	______	0=not breathless, 10=breathless X = too breathless to respond
xi. Glasgow Coma Score verbal	____ / 5	____ / 5	
xii. Glasgow Coma Score eye-opening	____ / 4	____ / 4	
xiii. Glasgow Coma Score motor	____ / 6	____ / 6	

Section C: Your treatment

Treatment	Administered?	If yes, which drug?	Dose? (if infusion, max rate of infusion attained in ml per hour within first 2 hours)	Route?
Nitrates	Yes ◯ No ◯	______	______	______
Opiates	Yes ◯ No ◯	______	______	______
Diuretics	Yes ◯ No ◯	______	______	______

Other medications and interventions (please specify):

The 3CPO Study | *ISRCTN: 07448447* | Study number: ☐☐☐☐☐ | Form number: ☐☐☐☐

Section D: Past medical history

Please tick 'yes' or 'no' for all questions.

Myocardial infarction	Yes	◯	No	◯
Angina	Yes	◯	No	◯
Percutaneous coronary revascularisation	Yes	◯	No	◯
Coronary artery bypass graft	Yes	◯	No	◯
Coronary heart disease (not otherwise specified)	Yes	◯	No	◯
Heart failure	Yes	◯	No	◯
Valvular cardiac disease	Yes	◯	No	◯
Any other cardiac disease	Yes	◯	No	◯

If OTHER, please specify: _______________

Chronic obstructive pulmonary disease	Yes	◯	No	◯
Cerebrovascular accident	Yes	◯	No	◯
Peripheral vascular disease	Yes	◯	No	◯
Hypertension	Yes	◯	No	◯
Diabetes	Yes	◯	No	◯
Hypercholesterolaemia	Yes	◯	No	◯
Family history of premature CHD	Yes	◯	No	◯
Current smoker	Yes	◯	No	◯

If YES, number of cigarettes per day: _____________

Ex-smoker	Yes	◯	No	◯
Any other chronic disabling illness	Yes	◯	No	◯

If OTHER, please specify: _______________

Patient's usual MRC breathlessness score (1–5 – see below) _____________

MRC breathlessness score

1. I only get breathless with strenuous exercise
2. I get short of breath when hurrying on the level or up a slight hill
3. I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level
4. I stop for breath after walking 100 yards or after a few minutes on the level
5. I am too breathless to leave the house

The 3CPO Study

ISRCTN: 07448447

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Section E: Pre-hospital treatment

Treatment	Administered?	If yes, which drug?	Dose?	Route?
Nitrates	Yes ◯ No ◯	______	______	______
Opiates	Yes ◯ No ◯	______	______	______
Diuretics	Yes ◯ No ◯	______	______	______

Inspired oxygen concentration: __________ litres per minute

Other medication and interventions (please specify): ____________________

Section F: Regular medication

Please tick 'yes' or 'no' for all questions.

Inhaled beta agonists	Yes ◯	No ◯
Inhaled steroids	Yes ◯	No ◯
Oral theophylline/aminophylline	Yes ◯	No ◯
Oral steroids	Yes ◯	No ◯
Sublingual GTN	Yes ◯	No ◯
Diuretic	Yes ◯	No ◯
ACE inhibitor	Yes ◯	No ◯
Beta-blocker	Yes ◯	No ◯
Calcium-channel antagonist	Yes ◯	No ◯
Oral nitrates	Yes ◯	No ◯
Aspirin	Yes ◯	No ◯
Clopidogrel	Yes ◯	No ◯
Warfarin	Yes ◯	No ◯
Nicorandil	Yes ◯	No ◯
Aldosterone receptor antagonist	Yes ◯	No ◯
Other	Yes ◯	No ◯

If OTHER, please specify: ______________

Please leave the form in the trial folder for the research nurse to complete.

Thank you.

Sections G J to be completed by the research nurse only.

Section G: Complications within 24 hours *not specifically related to CPAP or NIPPV*

Details of complications specifically related to CPAP or NIPPV should not be recorded here, but in section H below.

Vomiting	Yes	◯	No	◯
Gastric aspiration	Yes	◯	No	◯
Hypotension (systolic <90)	Yes	◯	No	◯
Arrhythmia requiring treatment	Yes	◯	No	◯
Pneumothorax	Yes	◯	No	◯
Progressive respiratory distress	Yes	◯	No	◯
Cardiorespiratory arrest	Yes	◯	No	◯
Any other complication	Yes	◯	No	◯

Please give details of all complications:

Section H: CPAP/NIPPV details and details of side effects within 24 hours if continuing beyond 2 hours

Length of time on active intervention (CPAP/NIPPV) (hours):
<6 hours ◯ 6–11 hours ◯ 12–17 hours ◯ 18–23 hours ◯ 24 hours + ◯

Treatment tolerated? Yes ◯ No ◯

If NO please give further details:

Side effects due to active intervention (CPAP / NIPPV):

Facial skin necrosis	Yes	◯	No	◯
Face discomfort	Yes	◯	No	◯
Increased breathing discomfort	Yes	◯	No	◯
Other side effect	Yes	◯	No	◯

If OTHER please specify:

The 3CPO Study ISRCTN: 07448447 Study number: ☐☐☐☐☐ Form number: ☐☐☐☐

Section I: Seven-day outcome data

Did the patient receive a treatment they were not allocated to receive (other than any treatment specified on page 1)? Yes ○ No ○

If patient recommenced on NIV please answer the following three questions. If multiple discrete episodes of NIV please only consider the first episode after trial intervention.

If YES, please state which treatment: CPAP ○ NIPPV ○

For how many hours after attendance was treatment administered? _______ hours

Length of time on treatment? _______ hours

<6 hours ○ 6–11 hours ○ 12–17 hours ○ 18–23 hours ○ 24 hours + ○

Has the patient undergone endotracheal intubation? Yes ○ No ○

If YES, how many hours after attendance was intubation performed? _______ hours

Is the patient alive at seven days? Yes ○ No ○

If NO, please record: Date of death: __ / __ / __ Cause of death:

Over the last 7 days, has the patient suffered any symptoms suggestive of MI after initial hospital attendance? Yes ○ No ○

If YES, how long after attendance was the worst pain? _______ hours / days

Please attach and label the following ECGs:

1. Any ECG recorded prior to this admission
2. The first recorded ECG
3. Any subsequent ECG recorded within two hours
4. Any subsequent ECG recorded between two and 24 hours
5. Any subsequent ECG recorded between 24 hours and seven days

Please detail results of any biochemical cardiac markers since admission:

Test used (name)	Sample no	Date of sample	Time of sample	Result
______________	1	__ / __ / __	____ : ____	______________
______________	2	__ / __ / __	____ : ____	______________
______________	3	__ / __ / __	____ : ____	______________
______________	4	__ / __ / __	____ : ____	______________
______________	5	__ / __ / __	____ : ____	______________
______________	6	__ / __ / __	____ : ____	______________
______________	7	__ / __ / __	____ : ____	______________
______________	8	__ / __ / __	____ : ____	______________
______________	9	__ / __ / __	____ : ____	______________
______________	10	__ / __ / __	____ : ____	______________

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Section J: 30-day outcome data

Is the patient alive at 30 days? Yes ◯ No ◯

If NO, please record: Date of death: __ / __ / __ Cause of death:

Location at 30 days Hospital ◯ Home ◯ Other ◯

If HOME, please check that the address is the same as that recorded on the front sheet

If OTHER, please specify: Address

Postcode

Total length of hospital stay: ____________ days

Number of ward days spent in hospital: ____________ days

Number of days spent on ITU: ____________ days

Number of days spent on CCU: ____________ days

Number of days spent on HDU ____________ days

Has the patient undergone:

PTCA or coronary stenting?	Yes	◯	No	◯
Coronary artery bypass grafting?	Yes	◯	No	◯
Any other cardiac surgery?	Yes	◯	No	◯

If OTHER please specify: ____________________

Has the patient received:

Echocardiogram	Yes	◯	No	◯
Thallium scanning	Yes	◯	No	◯
Intravenous thrombolysis	Yes	◯	No	◯
Glycoprotein IIB/IIIA inhibitors	Yes	◯	No	◯
Cardiac inotropes	Yes	◯	No	◯
Intra-aortic balloon pump	Yes	◯	No	◯