Clinical trial results:
Will titrated oxygen flow to a peripheral oxygen saturation of 88-92% compared with oxygen flow to a saturation >94% reduce mortality in Chronic Obstructive Pulmonary Disease patients with acute exacerbation? – a randomized clinical trial

Summary

EudraCT number	2019-002498-80
Trial protocol	DK
Global end of trial date	12 November 2025

Results information

Result version number	v1 (current)
This version publication date	28 November 2025
First version publication date	28 November 2025

Trial information

Trial identification

Sponsor protocol code	06062019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05052125
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hospital of South West Denmark
Sponsor organisation address	Finsensgade 35, Esbjerg, Denmark,
Public contact	Mikkel Brabrand, Research Unit in Emergency Medicine, SVS, 0045 40736373,
Scientific contact	Mikkel Brabrand, Research Unit in Emergency Medicine, SVS, 0045 40736373,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 November 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 November 2025
Global end of trial reached?	Yes
Global end of trial date	12 November 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine if titrated supplementary oxygen treatment to a low peripheral oxygen saturation initiated at arrival to the emergency department is superior to supplementary oxygen treatment titrated to a high peripheral oxygen saturation in reducing 30-day all-cause mortality in acutely admitted patients with COPD exacerbation.

Protection of trial subjects:

Close follow-up by study nurses.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 July 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3
From 65 to 84 years	15
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

Patients were screened by study nurses and offered inclusion if they fulfilled the criteria in the ED.

Pre-assignment

Screening details:

Patients were screned on arrival to the ED and included within 30 minutes by study nurses if they fulfilled the criteria.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Target peripheral oxygen saturation of 88-92%

Arm type	Experimental
Investigational medicinal product name	Oxygen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

Titrated to desired peripheral oxygen saturation

Arm title	Control

Arm description:

Control

Arm type	Active comparator
Investigational medicinal product name	Oxygen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

Titrated to desired peripheral oxygen saturation

Number of subjects in period 1	Intervention	Control
Started	12	11
Completed	12	11

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	23	23	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	75		
inter-quartile range (Q1-Q3)	68 to 84	-	
Gender categorical Units: Subjects			
Female	14	14	
Male	9	9	
COPD diagnosis on inclusion			
Did the patient have a COPD diagnosis registered at time of inclusion			
Units: Subjects			
Yes	23	23	
No	0	0	
Unknown	0	0	
Transportion time			
Time spent on transportion to hospital via ambulance			
Units: minute			
median	29		
inter-quartile range (Q1-Q3)	15 to 30	-	

Subject analysis sets

Subject analysis set title	Intention-to-treat analysis
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Analysis according to randomisation

Reporting group values	Intention-to-treat analysis		
Number of subjects	23		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
median	75		
inter-quartile range (Q1-Q3)	68 to 84		
Gender categorical			
Units: Subjects			
Female	14		
Male	9		
COPD diagnosis on inclusion			
Did the patient have a COPD diagnosis registered at time of inclusion			
Units: Subjects			
Yes	23		
No	0		
Unknown	0		
Transportion time			
Time spent on transportion to hospital via ambulance			
Units: minute			
median	29		
inter-quartile range (Q1-Q3)	15 to 30		

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: Target peripheral oxygen saturation of 88-92%	
Reporting group title	Control
Reporting group description: Control	
Subject analysis set title	Intention-to-treat analysis
Subject analysis set type	Intention-to-treat
Subject analysis set description: Analysis according to randomisation	

Primary: 30-day all-cause mortality

End point title	30-day all-cause mortality
End point description:	
End point type	Primary
End point timeframe: 30-days after inclusion	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: Patients				
Alive at 30 days	12	8		
Dead at 30 days	0	3		

Statistical analyses

Statistical analysis title	Fischers exact test
Comparison groups	Intervention v Control
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.093
Method	Fisher exact

Secondary: 7-day all-cause mortality

End point title	7-day all-cause mortality

End point description:

End point type	Secondary

End point timeframe:
7 days after inclusion

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: Patients				
Alive at 7 days	12	10		
Dead at 7 days	0	1		

Statistical analyses

Statistical analysis title	Fischers exact test
Comparison groups	Intervention v Control
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.478
Method	Fisher exact

Secondary: Non-invasive ventilation

End point title	Non-invasive ventilation

End point description:

End point type	Secondary

End point timeframe:
During hospital admission

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: Patients				
Received non-invasive ventilation	1	1		
Did not receive non-invasive ventilation	11	10		

Statistical analyses

Statistical analysis title	Fischers exact test
Comparison groups	Intervention v Control
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Secondary: Admission to intensive care

End point title	Admission to intensive care

End point description:

End point type	Secondary

End point timeframe:

During hospital admission

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: Patients				
Admitted to intensive care	0	1		
Not admitted to intensive care	12	10		

Statistical analyses

Statistical analysis title	Fischers exact test
Comparison groups	Intervention v Control
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.478
Method	Fisher exact

Secondary: Intubated during admission

End point title	Intubated during admission

End point description:

End point type	Secondary

End point timeframe:
During hospital admission

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: Patients				
Intubated	0	0		
Not intubated	12	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of hospital admission

End point title	Length of hospital admission

End point description:

End point type	Secondary

End point timeframe:
Total length of hospital stay

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: day				
median (inter-quartile range (Q1-Q3))	4.0 (2.1 to 4.3)	3.1 (3.0 to 7.0)		

Statistical analyses

Statistical analysis title	T-test
Comparison groups	Intervention v Control
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.179
Method	t-test, 2-sided

Other pre-specified: Systemic oxydative stress level (8-isopropane)	
End point title	Systemic oxydative stress level (8-isopropane)
End point description:	
End point type	Other pre-specified
End point timeframe:	
4 hours after inclusion	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	9		
Units: picogram(s)				
median (inter-quartile range (Q1-Q3))	19.1 (14.75 to 44.75)	16 (5.4 to 16.5)		

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Intervention v Control
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021
Method	Wilcoxon (Mann-Whitney)

Other pre-specified: Systemic inflammation level (IL-8)	
End point title	Systemic inflammation level (IL-8)
End point description:	
End point type	Other pre-specified
End point timeframe:	
4 hours after inclusion	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	9		
Units: picogram(s)				
median (inter-quartile range (Q1-Q3))	30.55 (8.55 to 55.45)	24.2 (11.4 to 42.4)		

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Intervention v Control
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.81
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 4 hours after inclusion	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	2.1

Reporting groups	
Reporting group title	Hypotension

Reporting group description: -

Serious adverse events	Hypotension		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Hypotension		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported