Clinical trial results:
The effect of oxygen on exercise performance in chronic heart failure

Summary

EudraCT number	2014-003380-38
Trial protocol	GB
Global end of trial date	05 November 2014

Results information

Result version number	v1 (current)
This version publication date	19 June 2019
First version publication date	19 June 2019
Summary attachment (see zip file)	Publication extract (Publication summary.doc)

Trial information

Trial identification

Sponsor protocol code	Oxyperform

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Hull and East Yorkshire Hospitals NHS Trust
Sponsor organisation address	Anlaby Road, Hull, United Kingdom, HU3 2JZ
Public contact	Professor Andrew Clark, Academic Cardiology department, A.L.Clark@hull.ac.uk
Scientific contact	Professor Andrew Clark, Academic Cardiology department, 675312 461775, A.L.Clark@hull.ac.uk

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	31 December 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does short-term oxygen affect exercise capacity in patients with chronic heart failure?

Protection of trial subjects:

Patients will normally remain within the trial for 2 months from consent.

Patient participation in the trial will be discontinued if:
- the patient withdraws consent
- the patient opts to discontinue participation
- the patient is withdrawn from the trial by the treating physician or medical researcher

All subjects may withdraw at any time from the study. For any subject withdrawing from the trial, permission will be sought to use the data collected to the point of withdrawing. If patients wish their entire data set to be withdrawn from the trial, they may notify the principal investigator.

Background therapy: -

Evidence for comparator:

Breathlessness is a prominent symptom in heart failure. The use of home oxygen has proven efficacy in conditions such as COPD with a number of meta-analyses confirming its role in improving symptoms of breathlessness. A number of studies have looked into the effect of oxygen therapy on breathlessness.

Actual start date of recruitment	25 August 2014
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	United Kingdom: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	8
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients are identified from heart failure clinics. After giving consent they will be randomized via computer generation to receive either (a) room air (21% oxygen) (b) 28% oxygen or (c) 40% oxygen delivered via venturi mask following baseline investigations. Patients will be blinded to the oxygen concentration being received.

Pre-assignment

Screening details:

Inclusion Criteria:

- Over 18 and able and willing to give consent
- Have symptomatic heart failure on medical therapy
- Able to use ergometer safely
- Impaired left ventricular systolic function (at least “moderate” on echocardiography or ejection fraction <40% by any technique)

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Only the members of the research team administering the oxygen will be aware of the concentration being investigated.

Arms

Are arms mutually exclusive?	Yes
Arm title	Room air

Arm description:

No oxygen concentrator mask used.

Arm type	dummy oxygen concentrator

No investigational medicinal product assigned in this arm

Arm title	28% o2

Arm description:

Venturi mask used to generate an o2 concentration of 28%.

Arm type	venturi oxygen concentrator
Investigational medicinal product name	Venturi mask
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pressurised inhalation
Routes of administration	Buccal use

Dosage and administration details:

It was necessary to put something here due to the shortcoming of the database.

Arm title	40% o2

Arm description:

Venturi mask used to deliver an 02 concentration of 40%

Arm type	venturi oxygen concentrator

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Room air	28% o2	40% o2
Started	11	10	10
Completed	11	10	10

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	31	31	
Age categorical Units: Subjects			
Adults (18-64 years)	7	7	
From 65-84 years	24	24	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	7	7	
Male	24	24	

End points

End points reporting groups	
Reporting group title	Room air
Reporting group description: No oxygen concentrator mask used.	
Reporting group title	28% o2
Reporting group description: Venturi mask used to generate an o2 concentration of 28%.	
Reporting group title	40% o2
Reporting group description: Venturi mask used to deliver an 02 concentration of 40%	

Primary: Exercise capacity	
End point title	Exercise capacity
End point description:	
End point type	Primary
End point timeframe: 2 weeks (3 exercise tests)	

End point values	Room air	28% o2	40% o2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	10	10	
Units: VO2				
number (not applicable)	11	10	10	

Statistical analyses

Statistical analysis title	t-test
Comparison groups	Room air v 28% o2 v 40% o2
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 30 days post final exercise test.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21

Reporting groups	
Reporting group title	non serious AE

Reporting group description: -

Serious adverse events	non serious AE		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	non serious AE		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Musculoskeletal and connective tissue disorders			
Muscle strain			
subjects affected / exposed	1 / 1 (100.00%)		
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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26891754