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NEON: North East Oxygen Network study

Submission date 05/06/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/07/2008	**Overall study status** Completed	
Last Edited 24/09/2015	**Condition category** Circulatory System	

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
HTA 06/80/01; Version 1

Study information

Scientific Title

Does home oxygen therapy (HOT) in addition to standard care improve disease severity and symptoms in chronic heart failure?

Acronym
NEON

Study objectives
What is the role of home oxygen therapy (HOT) in the management of patients with chronic heart failure (CHF)? To address the current uncertainties in patients with New York Heart Association (NYHA) class III/IV chronic heart failure with regard to the place of oxygen therapy in their management. This is a feasibility study (Stage 1) conducted in preparation for the main (Stage 2) randomised controlled trial.

On 10/09/2009 the overall trial start and end dates were updated from 01/09/2008 and 01/12/2009 to 01/01/2010 and 31/12/2010, respectively.

On 05/07/2013 the overall trial end date was updated from 31/12/2010 to 01/01/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Research Ethics Committee, 24/08/2009, ref: 09/H0903/42

Study design
Prospective four-arm multicentre randomised feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Heart failure

Interventions
The participants will be randomised to receive HOT as nocturnal oxygen therapy (NOT) or long-term oxygen treatment (LTOT). Once randomised to one of the two modes of oxygen delivery,

there will be a second randomisation to active oxygen therapy or sham (placebo) therapy. This stage of the study will be double-blind. The first and second randomisations will each be in 1:1 ratio.

Total duration of interventions: 3 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To assess the feasibility of the proposed randomised control trial in the following regard:
1. Prevalence of hypoxaemia in patients with NYHA III/IV and optimal medical therapy.
Assessment of arterial oxygenation by:
1.1. Arterial saturation by pulse oximetry at baseline and at the completion of the 6 minute walk test
1.2. Overnight oximetry using the Embletta® to record (i) nadir of oxygenation overnight (ii) proportion of night time spent with oxygen saturation below 95%
2. Recruitment and retention of study patients and their compliance with trial intervention.
Criteria for proceeding to the larger RCT phase of the study:
2.1. Recruitment rate >= 3 patients per week per centre during the recruitment phase
2.2. Drop out rate (excluding deaths) of <= 15% at 3 months
2.3. Compliance >= 27%
Number of hours of oxygen used will be measured by concentrator meter and patient diaries.
3. The value of the intervention for a preliminary cost-effectiveness analysis: Minnesota Living with Heart Failure (MLwHF) quality of life questionnaire scores at baseline, 1 and 3 months.
4. To develop a cost-effectiveness model of HOT based on existing evidence (to asses the likely benefit of proceeding to the larger RCT phase of the study)
5. Expected value of perfect information (EVPI) associated with the data to be collected in the proposed trial, that is, whether the patient benefits from the improvement in treatment decisions possible with the additional information provided by the trial is worth the cost of undertaking a definitive clinical trial of this intervention. To use this to inform the design of the subsequent main trial.

Secondary outcome measures
1. To assess the effect of HOT delivered as NOT or LTOT on the following:
1.1. Symptoms (total duration of follow-up: 3 months):
a. Assessed using the results of standard biochemistry tests
b. 6 minute walk test
c. Prevalence of hypoxaemia results
d. Validated Borg score and Numerical Rating Scale (NRS) for breathlessness (average and worse over past 24 hours and current level)
d. Change in validated Karnofsky performance scale of physical activity
e. Epworth Sleepiness score to assess daytime somnolence
f. Co-morbidity measured by the Charlson co-morbidity index
1.2. Quality of life, as measured by MLWHF, Hospital Anxiety and Depression (HAD) (mood assessment) and EuroQoL questionnaires at baseline, 1 and 3 months
1.3. Disease severity in patients with CHF, as measured by the validated Borg score and NRS for breathlessness (average and worse over past 24 hours and current level). Total duration of

follow-up: 3 months
2. To assess the cost-effectiveness of HOT (see 3 in Primary outcome measures)
3. To assess the acceptability to patients and carers of study intervention and placebo device (Patient diary at enrolment, 1 and 3 months)
4. To assess the acceptability of the placebo device to clinicians (through communications with the research teams)

Overall study start date
01/01/2010

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 years or over
2. Heart failure grade NYHA III/IV with left ventricular (LV) systolic dysfunction confirmed by echocardiography. The left ventricular ejection fraction must be less than 40% or graded as at least "moderately" impaired on visual inspection if an accurate ejection fraction cannot be calculated
3. Heart failure from any aetiology
4. Maximally tolerated medical management of their heart failure
5. Provided written informed consent and able to complete patient assessments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
Patients who:
1. Are unable to provide informed consent
2. Are unable to complete patient related information on entry
3. Have chronic obstructive pulmonary disease (COPD) likely to fulfil criteria for long-term oxygen treatment (LTOT); forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) <70% and FEV1 <40% predicted and hypoxia (pO2 <7.3 kPa or saturations <90%)
4. Have co-existing malignant disease if this would affect the study in the investigators' opinion

5. Patients with persistent basal pulmonary crackles found to have interstitial lung disease
6. Unwilling or unable to comply with safety regulations regarding oxygen use, particularly smoking

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Castle Hill Hospital
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/09/2015		Yes	No
HRA research summary			28/06/2023	No	No