# **NEON: North East Oxygen Network study**

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

## Plain English summary of protocol

Not provided at time of registration

## **Contact information**

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Treatment

## 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(s)

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.

#### Key secondary outcome(s))

- 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)

## 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

#### Healthy volunteers allowed

No

#### Age group

Adult

### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre Castle Hill Hospital

Cottingham United Kingdom HU16 5JQ

## Sponsor information

## Organisation

University of Hull (UK)

#### **ROR**

https://ror.org/04nkhwh30

## Funder(s)

#### Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

#### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

#### Location

United Kingdom

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

### **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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes