The HOT Study

Does Home Oxygen Therapy (HOT) in Addition to Standard Care Reduce Disease Severity and Improve Symptoms in Patients with Chronic Heart Failure?

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of the study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

1. What is the purpose of the study?

Home Oxygen Therapy can be given in a patient's own home by installing an oxygen concentrator machine. This filters ordinary room air to concentrate the oxygen, and then delivers it through a narrow tube to the patient. Therapy can be delivered overnight and for several hours during the daytime, too – at least 15 hours out of the 24 (long term oxygen therapy).

Home Oxygen Therapy is a proven treatment to help people with longstanding lung problems and low oxygen blood levels. Sometimes it is used to try and help the breathlessness that can be caused by heart failure. However, we do not know whether it does actually help patients with heart failure or not, or, if it does, whether night time or long term oxygen is more effective.

As the treatment itself is quite expensive, and can cause a burden because of the equipment needed, we feel it is important to ask these questions: is it helpful, do patients find it a burden, and how should we give it?

We are testing to see whether having extra oxygen delivered by the concentrator makes a difference to your symptoms, blood oxygen levels and degree of heart failure.

In this study, we will compare patients who do not receive Home Oxygen Therapy to those who receive it for 15 hours during the day and overnight. We intend to invite 222 patients from different hospitals to participate in this study.

2. Why have I been chosen?

We have invited you to participate in our study because you have been identified as having heart failure causing symptoms such as breathlessness.

3. Do I have to take part?

No. It is entirely up to you to decide. We will discuss the study and go through this information sheet, which we will then give to you. After you have had time to decide about taking part, we will then ask you to sign a consent form to show you have agreed.

You are free to withdraw at any time, without giving a reason. Should you wish to withdraw you should let your local clinical team know or write/call the York Clinical Trials Unit (see page 9). This would not affect your usual care, or effect your relationship with your doctor or the hospital staff. The only information that we will keep for research and analysis is what has been collected about you until the time you decide to stop participating in the trial.

4. What are the alternatives for treatment?

You are already receiving the optimal medication known to be effective for your condition. This study is looking at an additional treatment, rather than an alternative one.

5. What will happen to me if I take part?

After you sign the consent form, you will be randomised (a process by which a computer determines by chance which treatment you receive) to receive long term oxygen therapy for 15 hours a day or no oxygen therapy. You would remain on this treatment for at least six months. Some people may stay on the study for longer, up to a maximum of 2 years, depending on when they start the trial. We will tell you how long we expect you to stay in the trial before you agree to join the trial. The study will not interfere with your current medication. You can withdraw from the study at any time, without giving a reason.

Start of the study

We will invite you to attend the clinic at <insert hospital name>. At the hospital, we need to measure your degree of heart failure, and how much trouble it causes you at the start of the study so we can see whether the home oxygen therapy makes any difference. We will do this by asking you to fill out some questionnaires and to undergo some tests described below many of which you may already have had during your treatment for heart failure:

- Pulse, blood pressure and breathing rate
- A walk test (in which you will walk up and down a corridor within the clinic for up to 6 minutes)
- An oxygen blood level measurement (done with a simple monitor that clips onto your finger and reads the oxygen level in the blood through your skin – this takes about a minute) to observe the level of oxygen in your blood will be performed before and after the 6 minute walk test
- A blood test to measure a substance in the blood that gives an indication of the degree of heart failure (called NT-proBNP)

- An echocardiogram (to obtain an ultra-sound picture of your heart)
- Questionnaires that ask about your symptoms, other illnesses, how you manage day to day and how much your heart failure affects your life and your mood. One of the questionnaires will also ask you about how well you sleep

We envisage that each visit will last 60-90 minutes.

- You may be asked to complete an overnight sleep test. This is a simple painless test that measures your breathing pattern and the levels of oxygen in your blood overnight. We show you how to use the machine at home, and we will collect the machine after you have completed the test. Your consultant or research nurse will advise you whether you will have a sleep study or not. [This section to be deleted at sites not undertaking the sleep study.]

If you are randomised to receive a home oxygen concentrator, we will arrange for it to be delivered and installed in your home. You will be shown how to use it, and be given a leaflet about the machine (attached). You can contact the research nurse, the company, or your clinician in the event of any problem or query (please see page 9 for contact details). The NHS will pay for the electricity costs of the machine (attached).

At 3 months

You will see the study nurse again at 3 months for the following:

- Pulse, blood pressure and breathing rate
- A blood test
- Questionnaires that ask about your symptoms and how you manage day to day.

We envisage that this visit will last 30-45 minutes.

If you don't need to be at the hospital, and prefer to be seen at home or a local clinic, then the nurse will visit you there.

At 6 months

We will repeat all the tests that we did at the start, except for the echocardiogram.

This will be done alongside your normal hospital appointment at <insert hospital name>.

We envisage that each visit will last 60-90 minutes.

At 12 months

We will repeat all the tests that we did at the start.

This will be done alongside your normal hospital appointment at < hospital name>.

We envisage that each visit will last 60-90 minutes.

If you stay in the trial longer than a year, then you would have another assessment at 18 months (the same as the 6 months visit), and possibly an assessment at 24 months (the same as the 12 months visit). Both of these visits would happen alongside your routine clinic visits to the <insert hospital name>.

When you have completed the trial, we will arrange for removal of the oxygen concentrator, if that is what you were randomised to receive. If you have found the oxygen concentrator beneficial, and wish to continue treatment with it, we will leave it in place.

6. What will I have to do?

There are no drugs involved in this study. Normal room air contains 21% oxygen. The concentrator devices deliver increased oxygen (28%) to the nostrils through a narrow tube. We are testing to see whether having extra oxygen delivered by the concentrator makes a difference to your symptoms, blood oxygen levels and degree of heart failure.

You will attend your normal 6 monthly clinics at <insert hospital name>, and will undergo some additional tests alongside your normal tests, and complete some questionnaires (these are described above). It may be more comfortable for you to attend in loose fitting clothes with comfortable walking shoes for the 6 minute walk test.

We will do one additional assessment when you have been in the trial for 3 months. This would normally occur in your home, with a nurse visiting you, but may be in hospital or a local clinic, depending on your needs and preferences. This assessment comprises of some minor tests and questionnaires (these are described above).

If you are randomised to receive an oxygen concentrator, we will arrange for it to be installed in your home after you start the trial, and uninstalled when you complete the trial. If you have found the home oxygen therapy useful, you can continue to use the oxygen concentrator.

7. What does having an Oxygen Concentrator involve?

A concentrator machine concentrates the oxygen from normal room air to provide a continuous supply of higher concentration of oxygen than normal. A fully trained home-oxygen engineer will deliver the concentrator machine to your home, install it and provide you with all the necessary tubing. The engineer will instruct you in its use and you will be given instructions for simple weekly maintenance.

Modern concentrators are reliable, quiet, easy-to-use and most patients find them a convenient source of oxygen. The engineer will service the machine after 6 months of use. At the end of the study, the engineer will remove the concentrator. Any excess in your electricity bills due to the concentrator will be reimbursed.

During the study, an engineer will be available in office hours if there are problems with the machine and can be contacted through your study nurse <insert name and telephone number>. As there is no proven need for you to have oxygen, there will be no need for emergency repair and it will be safe for you to wait for office hours.

You are already receiving the optimal medication known to be effective for your condition. This study is looking at an additional treatment, rather than an alternative one.

If your medical condition should change such that it is thought that you do need oxygen therapy, that will be provided by your doctors in the usual manner.

8. Expenses and payments

We will pay for any reasonable travel expenses, and any excess electricity bills arising from the use of the oxygen concentrator. We will arrange and pay for the collection of overnight testing equipment from your home.

9. What are the possible disadvantages and risks of taking part?

The oxygen devices will take up a small amount of space and make a low humming noise which some people may find intrusive. Complying with safety measures will be important, particularly with regard to smoking.

Blood sampling may cause a small amount of bleeding, discomfort, or a bruise, and in very rare cases, infection. Occasionally a person may feel light headed when their blood is drawn.

10. What are the side effects of any treatment received when taking part?

In addition to the safety issues on page 7, you may experience some drying of nasal passages and pressure of tubing over tops of ears. Both can usually be helped with simple measures.

11. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study will help improve our understanding of the effects oxygen therapy in people with heart failure. We hope the information will allow us to answer the questions about oxygen therapy posed earlier, so we can recommend appropriate use for patients with heart failure throughout the NHS.

12. What happens when the research study stops?

If you feel a benefit from the home oxygen therapy, then you can continue to use it when you complete the trial. Otherwise, your routine care will continue as before.

Of course, if your condition should change during the study, such that you definitely need oxygen therapy anyway at the end of the study, then that will be provided as part of your usual management even when the study has ended.

13. What will happen if I don’t want to carry on with the study?

You are free to withdraw at any time for any reason. This will not affect your future care. If you withdraw from the study and you state that you do not want the information we

have collected about used in this study we will destroy all of the data we have collected about you.

14. What if there is a problem?

If you have a concern about any aspect of this study, please speak with the study nurse who will do their best to answer all your questions. You are welcome to discuss your concerns with other members of the clinical team. You may wish to contact the Patient Advice and Liaison Service. These contact details are listed on page 9.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during this study, the normal NHS complaints mechanisms are available to you. Information about patient rights, research-related questions and research-related injury can be obtained from the Local Patients Advice and Liaison Service or the British Heart Foundation.

15. What if something goes wrong?

In the unlikely event that something does go wrong and you are harmed, or feel you are harmed, during the research and this is due to someone's negligence then you may have grounds for a legal action against Hull and East Yorkshire NHS Trust.

16. Will my taking part in the study be kept confidential?

Yes. All information collected about you during the course of the study will be kept strictly confidential and in accordance with The Data Protection Act 1998 and no information by which patients can be identified will be reproduced or disclosed. Your GP and his/her General Practice will be notified of your participation in the study, with your permission. The personal data recorded on all records will be regarded as confidential, and to preserve each patient's anonymity, only your initials and date of birth will be recorded on the forms associated with the study. Patients will be identified by the use of a unique trial number allocated to them on entry into the study. The study doctor will use your personal data for the purposes of administering and conducting the study and will ensure that strict patient confidentiality is maintained. At a minimum, this data would include name, date of birth and relevant NHS patient identifiers as required. The data will also be accessible to approved members of the Clinical Trials Team including the University of York Trials Unit, and regulatory authorities for approved trial purposes only. The NHS approved oxygen supply company will provide the trial with readings from the home oxygen equipment. The data will be analysed in accordance with the European Union Directive on the protection of individuals with regard to the processing of personal data.

17. Contact Details:

Principal Local Investigator:
Research Nurse:
Regional oxygen supplier
Emergency contact:
Patient Advice & Liaison Service
British Heart Foundation:
York Clinical Trials Unit: Mrs Sarah Cockayne

If you wish to contact the research team by post for any reason, please write to: Mrs Sarah Cockayne, Research Fellow XXXX

Tel: XXXX

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

1. What if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study. If you and/or your research doctor decide you should not carry on, your research doctor will make arrangements for your care to continue. If your research doctor is happy for you to continue in the study, and you agree, he may ask you to sign an updated consent form. If the study is stopped for any other reason, we will tell you and arrange your continuing care.

2. What will happen to any samples I give?

Blood samples will be anonymised, stored, analysed and destroyed by your local hospital laboratory If they are not analysed for any reason, they will be destroyed. The anonymised analysis data will be passed to the University of York Clinical Trial Unit, who are overseeing data management for this trial.

3. Will any genetic tests be done?

No.

4. What about my General Practitioner?

We will inform your GP (with your permission) that you have been invited to participate in the study.

5. What will happen to the results of the research study?

These will be examined by the staff undertaking the study and published as appropriate in medical journals, for the benefit of other patients and research studies.

You will not be personally identified in any report/ publication. You may request results of the trial if you so wish. An executive summary will be prepared for patient heart failure support groups to see on request.

6. Who is organising and funding the research?

The research is funded by the Health Technology Assessment (HTA) programme, which is part of the Department of Health. The sponsor for the trial is Hull and East Yorkshire NHS Trust.

The research group is being led by Professor Andrew Clark from the Department of Academic Cardiology, Castle Hill Hospital, Hull. Data collection is being managed by the University of York Clinical Trials Unit. Both Hull and East Yorkshire NHS Trust and the University of York Clinical Trials Units are part of the Hull-York Medical School (HYMS).

7. Who has reviewed the study?

The Northern and Yorkshire REC has reviewed this study for adherence with medical and ethical standards and scientific value and has given a favourable ethical opinion for conduct in the NHS.

Thank you for reading this information. If you decide to take part in the trial you will be given a copy of this information sheet and signed consent form to keep.