NHS Logo

Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Headington
Oxford, OX3 7LE
Dr Chris Turnbull,
email: christopher.turnbull@ouh.nhs.uk
Tel: 07816655475
Prof John Stradling,
email: john.stradling@ouh.nhs.uk
Tel: 07831604811

PARTICIPANT INFORMATION SHEET
Study Title: The Feasibility of supplemental OXygen in patients with resistant hypertension and Obstructive Sleep Apnoea (FOX OSA)

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

High blood pressure that is not controlled by three or more medications is called resistant hypertension. Resistant hypertension can be made worse by other conditions including obstructive sleep apnoea (OSA). OSA is a condition that causes snoring, pauses in breathing during sleep, and dips in oxygen levels overnight. This study has two aims: 1) to see how common OSA is in patients with resistant hypertension attending the Oxford specialist hypertension clinic and 2) to see if using extra oxygen during sleep is feasible in patients with resistant hypertension shown to have OSA.

Why have I been invited?

We are looking for participants from the specialist cardiology hypertension clinic who have high blood pressure which is not controlled on three medications. We are not looking for participants with known OSA. You have been invited as your clinician thinks you would be appropriate for this study. We plan to recruit 20 participants in this study.

Do I have to take part?

No, it is entirely up to you to decide if you wish to join this study. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. Neither declining to enrol nor withdrawing from the study at any point in time will influence the clinical care you receive in any way.

What will happen to me if I decide to take part?

As the first step, we will make sure that you understand the study, and ask you to confirm this when the researcher completes the informed consent form with you. To reduce the number of hospital visits, we will explain the study in a virtual appointment by telephone or video-call. We will have sent you the Informed Consent form along with this Patient Information Leaflet by email so you will have copies of these for your reference during that call. If you agree to

participate in this virtual appointment, the researcher will document this in the consent form and provide you with a copy for your records.
With your permission, we will review your medical notes to check that you are suitable for this study. Following this, there are two stages to this study, an initial stage looking at whether you have OSA, and then a stage when we will ask you to use supplemental oxygen for two weeks. If you participate, this study will involve extra appointments outside of your normal clinic appointments. *Stage 1* involves two virtual appointments lasting approximately 20 minutes. Following stage 1, if you are suitable for *Stage 2*, this will involve two face-to-face appointments lasting 1-2 hours. In the event face-to-face visits are not permitted, these will instead be virtual. The study will involve sleeping two nights wearing a sleep study kit in *Stage 1* and using extra oxygen (described below) for two weeks in *Stage 2*.

Stage 1

This stage of the study will involve virtual appointments. One of the researchers will arrange a telephone call or video call. You will have the opportunity to ask any questions that you may have about the study. We will ask you some questions about any medical problems you have and write down details of your current medications. We will then arrange for you to collect, or post-out a home sleep study kit, home blood pressure monitor (see ***Figure 1***) and a participant diary to you. Once you have received these, we will arrange a second telephone call or video-call to run through how to use these. You will then be asked to use the overnight sleep kit for two nights whilst you sleep (See ***Figure 2***). This is a small device worn on your chest which connects to an oxygen probe which is worn on your finger and nasal prongs which sit in your nose. Once you have finished using your sleep kit for two nights, you will be asked to return the equipment to us in a stamped addressed envelope.

Figure 1: Photograph of the home blood pressure monitor you will be asked to use.

Figure 2: Photograph showing the overnight sleep kit that you will be asked to wear.

Once we have received your sleep kit, we will explain to you the results. If this does not show OSA, you will not be suitable to go onto *Stage 2* of the study and your participation in the study will end. If your study does show that you have OSA, you will be able to continue on to *Stage 2* of the study. Occasionally, these sleep studies do not provide suitable recordings to make a diagnosis. In which case there will be the opportunity to repeat the sleep studies up to twice. In this case, we will again either arrange collection or postage of the sleep kit with you.

Stage 2

Stage 2 involves two face-to-face visits, a baseline and a follow-up visit. We will phone you ahead of this appointment to check that you are well and to run through a COVID-19 safety check list. When visiting the hospital, we may ask you to wear a face covering (unless you are exempt), the study team may also wear personal protective equipment, and the risk of COVID-19 infection will be minimized. At your baseline visit you will be asked to complete a questionnaire about your sleep and how your sleep impacts your daily life. We will measure you blood pressure, heart rate, height, weight and neck circumference.

We will also take a 1ml blood sample from your earlobe to measure the levels of carbon dioxide in your blood. This is no more painful than a normal blood test. This blood test is analysed straight away and no blood will be stored in this study.

You will be provided with an oxygen concentrator, tubing and a given a choice of a face-mask or nasal prongs and shown how to use this. An oxygen concentrator is a machine which is about the same size as a mini-fridge. It concentrates oxygen from room air and delivers extra oxygen whilst you are sleeping via a face-mask or nasal cannulae. We will help you with getting this home if needed. It can be stored in a room nearby, up to 15m away, to your

bedroom to reduce the noise. You will be supplied with enough tubing to allow it to be placed where you would like (up to 15m away). Tubing should be pulled tight and stored away securely when not using the oxygen concentrator. You will be asked to turn the oxygen concentrator on immediately before going to sleep and to turn it off immediately when you wake up in the morning. It is not necessary to turn the oxygen concentrator off if you get up briefly in the night.

You will be provided with a pulse oximeter, which is a small device worn like a wrist-watch, and shown how to use this. You will then be instructed to sleep using both the oxygen concentrator and pulse oximeter for the next 14 nights.

In the event face-to-face visits are not permitted, this visit will instead be virtual. In this case, we will not take a blood test from your earlobe and will supply all of the equipment you will need ahead of this visit. If this appointment is virtual we will supply you with a single use tape measure and ask you to record your own height, weight and neck circumference if possible.

After 14-17 nights, we will arrange for you to come back to have a follow-up visit. At your follow-up visit you will again be asked to complete a questionnaire about your sleep and how this impacts your daily life. We will measure you blood pressure and heart rate.

We will also take a repeat blood sample from your earlobe as on the first face-to-face visit.

We will collect your oxygen concentrator, pulse oximeter, blood pressure machine and participant diary from you. We will be able to help with returning these if needed.

In the event face-to-face visits are not permitted, this visit will instead be virtual. In this case, we will not take a blood test from your earlobe.

Whilst it will not be possible to continue oxygen treatment at the end of the study, as this is not yet approved as a treatment for OSA, there are approved treatments for OSA that we can discuss with you.

What should I consider?

Before deciding to take part, we encourage you to take some time to consider if you feel this would be the right thing for you. You will not be able to take part if you have surgery planned during the time of the trial but your participation could be delayed to allow you to recover from this surgery first. You will not be able to take part if you have taken part in any other research trial investigating any other medical product (such as a new drug treatment) within the last 12 weeks, although again your participation could be delayed until after these 12 weeks. You will not be able to take part if you are a professional driver, have any other vigilance critical job, or have used CPAP for obstructive sleep apnoea before. You will not be able take part if you or anyone else who lives with you smokes, due to an increased risk of fire with supplemental oxygen use.

During the trial you should continue all of your normal medications and over-the-counter medicines. There are no specific requirements in relation to contraception but if you become pregnant or think you might be pregnant during the trial we would ask you to inform us as we are not including pregnant women in this study. This is because we are not investigating the effects of oxygen treatment for blood pressure in women who are pregnant with OSA.

Are there any possible disadvantages or risks from taking part?

Before taking part, you should consider any potential disadvantages of the study.

***Stage 2* of this study involves the use of oxygen therapy. Oxygen is a flammable gas. When using oxygen therapy during *Stage 2,* it is important that no-one smokes in the house and that the oxygen or air concentrator does not come into contact with naked flames (e.g. candles) as this would pose a fire risk.**
Oxygen therapy can cause a dry or blocked nose. Rarely oxygen therapy can cause nose bleeds or morning headaches. If you experience either of these side effects, or any other side effects whilst using oxygen treatment, please contact the study team immediately.
If you agree to take part in this study, you will have to give up some of your time. You will commit to two virtual appointments lasting about 20 minutes and two face-to-face appointments each lasting 1-2 hours. (If these visits cannot be done face to face, they will be completed as virtual visits and will last about 1-1.5 hours). You will have to get used to new devices including a home sleep study kit, blood pressure machine, oxygen concentrator and a wrist watch to measure oxygen levels (pulse oximeter). Please do get in touch with us if you have any problems with these devices using the contact details provided below.
If you agree to this study, you will also agree to have two blood tests. These blood tests can be slightly painful but should not be any more painful than normal blood tests. There is also a very low risk of tissue damage although this is very unlikely and the test will be conducted by an experienced clinician.

You may be diagnosed with obstructive sleep apnoea (OSA) as part of this trial. OSA can cause sleepiness which can affect driving. If you are significantly sleepy, regardless of the cause, we would like to remind you not to drive.

What are the possible benefits of taking part?

Taking part in this study may show that you have undiagnosed OSA. If this identified, we can discuss your options for treating OSA at the end of the study.

Will my General Practitioner/family doctor (GP) be informed of my participation?

As a key person and gate keeper in coordinating your NHS healthcare, it is important that your GP is aware of your participation in this study especially when it is confirmed that you do have OSA. We will specifically ask your written consent to send out a letter to your GP explaining your participation in this study if you agree to enter.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential and any information about you which leaves the hospital will have your name and address removed so that you cannot be identified to anyone outside your research team. Your study data (apart from the consent form which will have your identifiable details) will be kept coded with a study number and only members of the research team will be able to identify you from that number. Your identifiable data will be kept securely within the Oxford University Hospitals NHS Foundation Trust. Any electronic records will be kept secure on password protected NHS computers and will only be accessible to the relevant research team members. The study data will be kept for 5 years after the study has finished (but any identifiable data will be destroyed within 12 months after the study has finished).

Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will be able to claim reasonable travel expenses for any research visits that are additional to your usual NHS care on production of receipts, or a mileage allowance provided as appropriate. You can discuss this with the research team if you require any additional details.

What will happen to the samples I give?

We would like to take up to two blood samples from you, both at your baseline and follow-up visit for the purpose of capillary blood sampling. These samples will be analysed immediately using a bedside blood gas analyser with any remaining blood being disposed of in accordance with the local procedures. No samples will be stored as part of this study.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible.

The Oxford University Hospitals NHS Foundation Trust will use your name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study for 6-12 months after the study has finished. After the study has finished the research team will archive copies of the consent forms and any other study records for 5 years.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Dr Chris Turnbull at

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time but will use the data and samples collected up to your withdrawal. Once you withdraw from the study, no further data or samples would be collected and no further research procedures would be carried out. Your withdrawal from the study will have no impact on your normal clinical care.

What will happen to the results of this study?

The results of this study will be submitted for publication in a medical journal with all study data anonymised. The study results may also be presented at conferences. Separately, providing you consent to this, we will send you a summary of the study results.

What if we find something unexpected?

If any of the study assessments produce findings of clinical significance for you, we will discuss it with you as further clinical verification and/or referral to your GP may be needed.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.
If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Chris Turnbull, email: christopher.turnbull@ouh.nhs.uk Tel: 07816655475
or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.
The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.
If you wish to contact the PALS team please contact them on 01865 235855 or at PALS@ouh.nhs.uk

How have patients and the public been involved in this study?

This research has been directly informed from recognising the priorities of patients. We surveyed patients with OSA from the membership of the Sleep Apnoea Trust Association, a patient led OSA support group. We received 585 responses to our survey of their membership. 85% of respondents either strongly agreed or agreed that “Developing new treatments, instead of CPAP, is important” and 70% either strongly agreed or agreed with the statement “Extra oxygen can be delivered via a face-mask that does not require a CPAP machine. Whilst this will not stop symptoms of sleepiness from OSA, it might help control blood pressure for some patients. Understanding if oxygen could be a new treatment option for OSA is important”.
You can find further information about taking part in research at:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

This study is sponsored by the University of Oxford. It is funded by the Oxford Health Services Research Fund and the Academy of Medical Sciences Starter Grants for Clinical Lecturers.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by East of England - Essex Research Ethics Committee.

Further information and contact details:

For any further information on the study please do not hesitate to contact the study team. The contact details are:
Dr Chris Turnbull (christopher.turnbull@ouh.nhs.uk Tel: 07816655475)

If you have a problem during the study please do not hesitate to get in touch with Dr Turnbull at any time. For urgent matters, if unable to get in contact with Dr Turnbull please contact the John Radcliffe Hospital switchboard on 01865 741166 and ask to be put through to the on call respiratory registrar.

Thank you for considering taking part.