Zeus-OSA Trial

Effect of transcutaneous electrical hypoglossal nerve stimulation on AHI in OSA patients

We invite you to take part in a research study

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends and family if you wish. You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from the NHS.

You are very welcome to ask us if there is anything that is not clear, or if you would like more information.

Important things that you need to know

We want to see if a stick-on device can help people with Obstructive Sleep Apnoea keep their airway open during sleep.

The study takes sixteen days, and you will be asked to come to three or four appointments at Dorset County Hospital, in Dorchester. It involves doing some at-home sleep studies and wearing different devices during sleep every night for two weeks. There's also a short daily questionnaire about your sleep quality and how you feel during the daytime.

We will repay reasonable travel costs for coming to appointments, and at the end of the study you will be given a brand-new device to keep.

Taking part or deciding not to take part will not impact on your current OSA treatment, or your place in the waiting list to start treatment. You can stop taking part in the study at any time.

In this research study we will use information from you and the sleep study devices you will wear. We will only use information that we need for the research study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

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How to Contact Us

If you want any more information, please contact the lead researcher:

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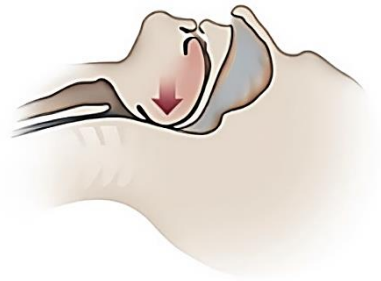
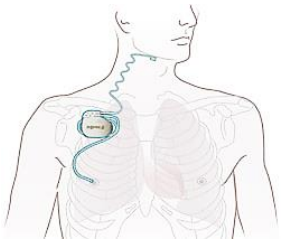
1. What is the study about?

Obstructive Sleep Apnoea (OSA) is caused by relaxation of the muscles of the tongue and throat during sleep, which causes snoring and narrowing or blockage of the airway. This leads to periods of low oxygen throughout the night which disrupts restful sleep. OSA severity is measured by the Apnoea-Hypopnoea Index (AHI) which tells us how many times per hour the patient's airway closes.



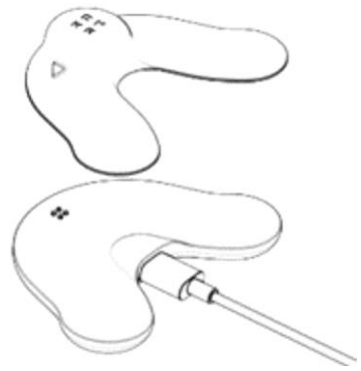
The international gold-standard treatment for OSA is Continuous Positive Airway Pressure (CPAP), which involves wearing a facemask attached by a hose to a CPAP machine. In the UK, CPAP is only routinely offered to people with moderate or severe OSA. People with mild OSA are usually asked to try making lifestyle changes like losing weight or stopping smoking at first.



An implantable device called Inspire uses gentle electrical signals to directly stimulate the nerves of the tongue and throat during sleep to keep the airway open without CPAP. This is currently being used to treat OSA in countries such as the USA and Canada, but it involves expensive invasive neurosurgery and is not yet available in the UK.

The Zeus device uses the same idea, but applies the gentle electrical stimulation through the skin, like a TENS machine. It uses a sticky pad to stick to the skin under the jaw. The first Zeus device has been shown to help improve snoring. It is CE marked and approved for sale in the UK.

We want to see if a Zeus device can be helpful for patients with OSA. If it's shown to be effective, it could be used as a treatment option for patients with mild OSA, or as part of treatment for patients with moderate or severe OSA who cannot use CPAP therapy.



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2. Who is taking part?

We are asking patients who have been diagnosed with OSA, but who are not currently using CPAP or other devices for treatment to take part in the study. You should be over 18 years old and have no other medical conditions which affect your sleep.

You will need to attend three or four appointments at Dorset County Hospital, in Dorchester, so you must be able to travel to us for these appointments. We will reimburse reasonable travel costs. You'll need to wear our equipment every night for two weeks. You'll also need to download and use an app on your smart phone. Taking part will not affect your current treatment plan. If you are waiting for CPAP or other treatment options, taking part will not change your place in the waiting list.

3. What do you have to do?

The whole study takes 16 days and involves doing home sleep studies and wearing Zeus devices. We will use two Zeus devices labelled A and B. One is 'active' and will be fully working, and one is 'sham', which will not work. Neither you nor the researchers will know which device is which, in order to keep the study fair.

We will do some simple measurements (height, weight and collar size) and ask you some questions about your sleep and how awake you feel during the daytime. We'll show you how to use the Zeus device, and the sleep study equipment. We'll also take some details so that we can reimburse you for reasonable travel expenses.

You'll be asked to do one baseline sleep study at home, then wear Zeus A during sleep for a week. On the last night of the week, you'll do another sleep study whilst wearing Zeus A. You'll attend a halfway appointment to swap the devices. Then you'll do the same thing again for a second week with Zeus B.

We'll also ask you to fill in a short questionnaire about your sleep every day and wear a small monitor like a ring on your finger every night. You will need you to download two free apps onto your smartphone to collect data from the Zeus device and the ring device via Bluetooth.

At the end, we'll see you one last time to collect all the equipment and questionnaires and to ask you your thoughts about the Zeus device and the study. We will refund reasonable travel costs and as a thank-you for completing the study, the inventor and manufacturer, Morgan IAT, will gift you a brand-new Zeus-1 device, which is currently being sold as an anti-snoring device in the UK and Europe.

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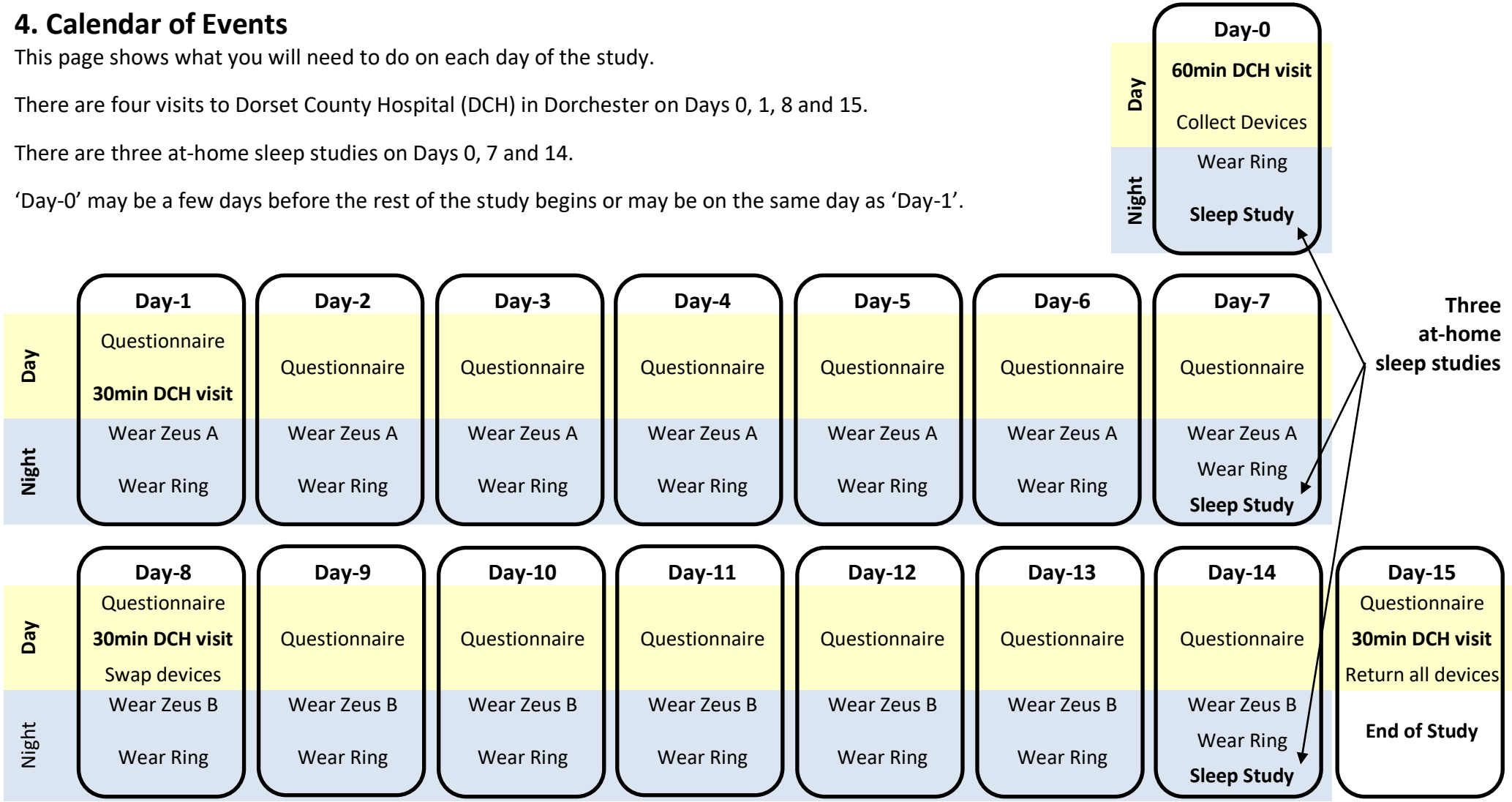
4. Calendar of Events

This page shows what you will need to do on each day of the study.

There are four visits to Dorset County Hospital (DCH) in Dorchester on Days 0, 1, 8 and 15.

There are three at-home sleep studies on Days 0, 7 and 14.

'Day-0' may be a few days before the rest of the study begins or may be on the same day as 'Day-1'.



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5. What are the benefits?

If you choose to take part in the study, you'll have an up-to-date sleep study performed which may offer you further information about your OSA and sleep quality. You'll also be providing us with vital information about a possible new treatment option to help OSA patients worldwide, and you may be a key part of helping us bring this new treatment to patients like you in the local area.

If you wish, we can add your baseline sleep report to your medical record so that you have an up-to-date sleep study available to other healthcare professionals involved in your care – this is entirely your choice, but you must let us know if you want us to do this before the end of the study as after then, all your data will be permanently anonymous.

6. What are the downsides and risks?

We don't expect there to be any significant risk for our participants. This study will not be investigating an untested technology but is looking how the Zeus device affects sleep quality specifically in OSA patients. The Zeus device is CE-marked and approved for commercial sale and use in snoring for the UK and EU. There's a small chance that the device or its adhesive may cause a minor localised irritation to your skin – if this happens, we would ask you to stop using the device immediately.

The study involves you wearing a Zeus device and sleep monitoring equipment every night for two weeks – although the equipment is all designed to be used during sleep and is as unobtrusive as we can manage, we are aware that wearing anything unfamiliar may make it harder to get a good night's rest. You may find that you are more tired or sleepy during the day – if this is causing you difficulties with your day-to-day tasks, we would ask you to take a few days off from the study, or to stop taking part.

7. Who is doing the research?

This research study is being run by the Respiratory and Sleep Physiology team at Dorset County Hospital, on behalf of the inventor and manufacturer of the Zeus device: Morgan IAT Ltd. The lead researcher is Catherine Morgan, who is the Chief Respiratory Clinical Physiologist at Dorset County Hospital.

The study has received funding from the National Institute for Health Research (NIHR), which is an independent UK organisation which regulates and promotes medical research.

Morgan IAT Ltd is providing the devices and some administration support but is otherwise not part of the data collection or data analysis. Dorset County Hospital is being reimbursed for their costs to run the study but receives no additional payment or benefit from the manufacturer or funder.

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8. What happens to my data?

We will need to use information from you and the sleep study devices you will wear for this research project. This information will include your name and contact details as well as your height, weight, collar size and how severe your sleep apnoea is. We will use this information to contact you during the research, to do the research itself, or to check your records to make sure that the research is being done properly.

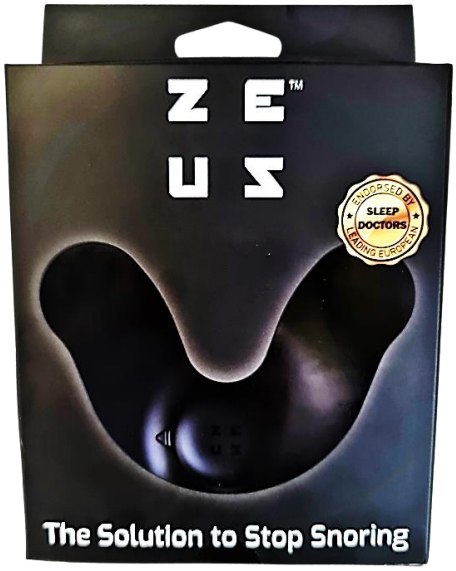
People who do not need to know who you are will not be able to see your name or contact details. Your data will have an anonymous code instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of your *anonymous* data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, unless you ask us not to. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients, by asking one of the research team, by sending an email to zeus@dchft.nhs.uk, or by ringing us on 01305 255 420.

9. What happens afterwards?

At the end of the study, we will collect back all the loaned equipment and all the questionnaires you've completed. We'll arrange for reimbursement for reasonable travel expenses, and we'll provide you with a brand-new Zeus device to keep as a thank-you for your participation.



Once we have collected data from all our participants we will process and analyse the information and write up a formal report of our findings, which we hope to publish in a medical journal such as the European Respiratory Journal or Thorax. When the report is finished, you will be emailed a summary of the findings and a link to download the full report if you want to read it. You can opt-out of receiving the final report if you want to.

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10. Frequently Asked Questions

Q. I think I have OSA but do not have a formal diagnosis. Can I still participate in the study?

A. Our study is specifically looking at how the Zeus device affects sleep quality in OSA patients; therefore, all our participants must have been diagnosed with OSA, ideally within the last two years.

Q. I was previously diagnosed with OSA, but my sleep has greatly improved since then. Can I still join?

A. Yes, this should be no barrier to joining the study.

Q. I would like to participate in the study, but I'm currently using CPAP. Can I still join?

A. Unfortunately, if you're using CPAP at the moment, we'd be unable to recruit you as a participant. This is because we need participants who do not wear any other devices during sleep. You cannot simply not wear your CPAP for our two-week study as this would be considered a 'withdrawal of treatment' and would require far greater medical and ethical scrutiny at every stage. For simplicity, we can only recruit participants who do not have a CPAP machine at home.

Q. I would like to participate in the study, but I'm currently using a sleep mouthpiece. Can I still join?

A. Similar to CPAP users, we cannot recruit participants who are using mouthguard devices to treat OSA or snoring as this would be considered a 'withdrawal of treatment' for the duration of the study. To keep our study simple and efficient, we can only recruit participants who do not use any other device whilst sleeping.

Q. I would like to participate in the study, but I don't live in Dorset. Can I still join?

A. All participants need to attend three or four in-person appointments at Dorset County Hospital, which is in Dorchester, so you must be able to reach us reliably. We are able to reimburse some travel costs but may not be able to cover the entire cost of your journeys if you live a long way away. Depending on how many participants apply, we may prioritise recruitment from the local area first, but we're happy to accept applications from anyone interested in participating.

If you have any other questions, please contact us at zeus@dchft.nhs.uk
or call us on 01305 255 420