ASSESSMENT AND MANAGEMENT OF OBSTRUCTIVE SLEEP APNOEA FOLLOWING BARIATRIC SURGERY

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What is this study about?

Obstructive sleep apnoea (OSA) is a sleep disorder where patients stop breathing or have extremely shallow breathing during sleep. Excess weight increases the risk of OSA. However, the majority of patients with OSA that present for weight loss surgery are unaware that they have OSA. OSA can be associated with an increased risk of complications following surgery. Complications can occur in relation to oxygen levels, breathing difficulties and heart problems.

Continuous positive airway pressure (CPAP) is a machine that blows air through a mask while you are sleeping. The pressure of the air keeps your throat open and makes your breathing easier while you sleep. CPAP is the preferred everyday treatment for OSA. However, it is unclear whether CPAP reduces the risk of complications following weight loss surgery in people with OSA.

As part of this study, we want to identify how common OSA is in people presenting for weight loss surgery. We also want to investigate whether the use of CPAP following weight loss surgery, in patients with OSA, is feasible and reduces the risk of complications.

Why am I being invited to participate in this study?

You are being invited to participate in this study because you are about to undergo weight loss surgery at Joondalup Health Campus (JHC).

What does participation involve?

In the initial phase of the study we will ask if you have previously been diagnosed with OSA, where that diagnosis was made, and if you are being treated for OSA. If you are already using CPAP for OSA, you will not participate in the remainder of the study and will continue to use your CPAP following surgery.

If you have not been diagnosed with OSA or are not using CPAP, we will ask you to participate in the second phase of the study. This will involve completing a short questionnaire assessing your risk of OSA and performing a simple home sleep test. The sleep test equipment will be provided to you with instructions and then can be posted back. The results of the sleep test will be analysed. If you are found to have OSA, you will be randomly assigned to either: standard postoperative care with continuous oxygen level monitoring and OSA monitoring; or postoperative CPAP therapy with continuous oxygen level monitoring. The CPAP machine that will be used is an auto-adjusting machine (APAP). You will be encouraged to use the APAP machine when you are asleep during the first day and night following surgery.

We will also need to collect information from your hospital records, which include your type of weight loss surgery, your medical history and your height and weight.

What are the benefits?

CPAP is the treatment of choice for OSA in the general population because it improves snoring and quality of sleep. This leads to less daytime sleepiness and fatigue.

What are the risks?

CPAP therapy is very safe with no severe side effects. There have been no reports of adverse events when it has been used on patients following weight loss surgery. It can be associated with short-lived discomfort related to skin irritation or nasal or throat discomfort. These resolve with stopping therapy or adjustment of the settings.

Do I have to participate?

Participation is entirely voluntary. Your relationship with JHC and the researchers will not be affected by declining to participate.

You are also free to withdraw at any time and without explanation. If you wish to withdraw, please ask to speak with one of the researchers.

This study is being run in conjunction with your surgery. Your surgery date, actual operation and post-operative follow-up will continue as planned regardless of whether you participate in this study, do not participate in this study or whether you commence the study then withdraw.

Confidentiality and privacy

Some of the information will form part of your hospital medical record and will be stored securely as required for this sort of information. The results from the questionnaire, sleep test and APAP machines will be stored by the investigators on password-protected computers. Your name will not appear on any data collected for research purposes.

What will happen with the findings?

The results will be presented to the Joondalup Health Campus departments of Anaesthesia, General Surgery and Intensive Care. We aim to publish the results in a journal. Your information and results will be de-identified when the results are presented and published.

Will I be told about my results?

If you are diagnosed with moderate or severe OSA we will send a letter to your GP (and copy this to yourself) outlining your diagnosis. Your OSA will need to be managed then reassessed following your weight loss, as the majority of patients will experience resolution of their OSA as they lose weight.

Who can I contact if I have any questions?

Dr Scott Claxton
Sleep & Respiratory Physician
Suite 103, Specialist Medical Centre, Joondalup Health Campus
9400 9886

This project has been registered as a clinical trial on the Australian New Zealand Clinical Trial Registry (www.anzctr.org.au) reference number: .

The ethical aspects of this study have been approved by the Joondalup Health Campus Human Research Ethics Committee (JHC HREC). If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact the JHC Executive Office on 9400 9404. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

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Consent form

Participant copy

I ……., give consent to participate in this study.

I agree that my hospital records and any previous sleep study records can be accessed to obtain information relevant to this study.

Signed (Participant): …… Date: ……

Signed (Investigator): ……. Date: ……

Have you previously been diagnosed with obstructive sleep apnoea?

YES/NO

If YES,
Where and when was the sleep study performed?

Are you on CPAP therapy?
YES/NO

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Investigator copy

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