GREENSLOPES PRIVATE HOSPITAL

PATIENT INFORMATION SHEET

Study Title: Can mandibular advancement improve CPAP effectiveness in patients sub-optimally treated with CPAP using an oronasal mask?

Principal Investigator: Dr Robyn O'Sullivan

Co-Investigators: Dr Tim Baird

The following information describes the clinical research study and your role as a participant. All participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

Your treating sleep physician or study coordinator will answer questions you may have about the study. The information contained in this information sheet will help you to understand the possible risks and benefits involved in the study, what alternatives are available, and what will happen. Your rights and responsibilities will also be outlined. Please note you will not receive any financial compensation for being a part of this study.

1. Purpose of the Study

You are invited to participate in this research study because you are using CPAP as your primary treatment for obstructive sleep apnoea (OSA) requiring an oronasal mask (full face mask) and your treating doctor has determined that your existing treatment is not adequately effective.

The purpose of this study is to test whether using a mandibular advancement device, the O_2Vent T, in combination with your existing treatment, will improve the control of your OSA.

The O_2Vent is an oral appliance that like other appliances, brings the lower jaw forward to help keep your airway open when you sleep. Oral appliances are safe and effective in treating snoring and sleep apnoea. The difference in the O2Vent T is the unique built in airway that allows users to breathe through the device.

Combination therapy is an option when singular treatment is not effective. Your treating doctor has determined that combination therapy is appropriate for your condition. You will not undergo any procedures, tests or visits that are not part of your usual care with combination therapy. However, the research team would like to collect data to evaluate how effective this type of treatment is.

2. Anticipated Duration

The duration of your participation will be approximately 2-3 months depending on how quickly your treatment can be optimised. There is considerable individual variation in how much jaw advancement is required to optimise treatment and how quickly this optimal position can be obtained so the anticipated duration is a guide only.

3. Investigators Benefits

This is an independent investigator led study. The Principle Investigator and Co-investigators are not receiving any remuneration from the manufacturers of CPAP or the dental appliance used in this study. However, Oventus Medical Limited, the manufacturer of the oral appliance, has agreed to pay for the costs of the devices as well as any auto-PAP rental that may be required as part of this study.

4. Expected Benefits

Possible benefits include an improvement in the treatment of your obstructive sleep apnoea. Others may benefit from this research as we gather more information on how best to treat sleep apnoea with a combination therapy approach.

5. Study Procedures:

Once your treating sleep physician has determined that combination therapy with CPAP and oral appliance is suitable for your condition and you have had the opportunity to review this information, ask questions and have signed the consent form, you will be asked to see a dentist with expertise in oral appliance therapy.

Once the dentist has checked that you are dentally suitable for a device, they will take impressions of your teeth and arrange a customised device to be made for you. This will take approximately 4 weeks. During this time, you will continue to use CPAP in an auto-titrating mode. If your machine is a fixed pressure machine, the research team will arrange an auto-PAP for you to use for the duration of this study.

After 4 weeks of CPAP use, your data will be downloaded and collected. You will then be fitted with your O_2Vent T and continue to use CPAP. The data will be downloaded after a week of combination therapy and reviewed, to determine if the lower jaw position needs to be adjusted further to provide additional improvement. If further advancement is required, this will take place slowly over a period of 8 weeks under the direction of your sleep physician and dentist's supervision. During this treatment acclimatisation and optimization time, you will have physician reviews and downloads as clinically indicated. Your dentist will also see you to ensure everything is going well with your oral appliance treatment. Once treatment has been optimised a final download will be performed.

Previous sleep study and download data may be reviewed as part of your care and collected as part of this study. We may wish to evaluate longer term treatment effects at your 6 or 12month review.

6. Risks and Discomforts:

The known risks and discomforts from using oral devices, like the O2Vent T, include excessive salivation; temperomandibular (jaw) joint pain; gum irritation; mouth dryness; jaw discomfort; tooth loosening; tooth wear; and protrusion of the lower jaw. Any discomfort related to the device usually resolves by taking the device out and discontinuing treatment. If you have any questions about these risks, please discuss them with a member of the research team.

As the effects of the device are unknown on unborn children you must not be pregnant at the start of the trial. If you are pregnant, you must tell the investigators who will ensure to treat your OSA using an alternative treatment. In the event you become pregnant during the course of the study, you will be immediately withdrawn from the study. You will be invited to give consent to allow access to information regarding any pregnancy and its outcome for the purpose of determining any effects from the study.

There are a number of visits/contacts with the dentist fitting the O_2Vent T, as well as with the research team to evaluate treatment. The exact number will depend on how quickly you get used to the device and how quickly treatment is optimized. There may be some inconvenience associated with the visits and tests required.

7. Your rights and responsibilities

There is no obligation for you to be involved in this study. If you do not participate your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future medical treatment. If you withdraw from the study you must return the O_2Vent T device to your dentist.

At the end of the study you may keep the O_2Vent T as it is a Class I device on the Australian Register of Therapeutic Goods.

Once the clinical trial has been completed and results have been analysed you will be contacted so that you can be notified of the results from the study.

You should advise the investigators of any other studies in which you are participating in.

If you require elective or emergency surgery or other medical care, you should inform the doctors looking after you about your participation in this research study.

In the event that combination therapy is not successful in treating your OSA, your treating sleep physician will discuss with you other treatment options.

8. Compensation for Injury

If, as a result of being in this study, you become ill or are injured, please contact your treating sleep physician or dentist immediately. They will then give you all necessary information and treatment and inform the manufacturer of any unanticipated device related adverse events.

As there are no procedures, tests or visits outside of your usual care, compensation for injury beyond your usual care is not applicable.

9. Ethics Approvals

The Greenslopes Research and Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint Procedure with someone not directly involved, particularly in

relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Greenslopes Research and Ethics Committee on Ph: (07) 3394 7819 or by email to researchandethics@ramsayhealth.com.au.

10. Confidentiality

Your records relating to this study and any other information from your medical records will be kept strictly confidential. Data will be collected, stored, used and disclosed in accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015) Section 3.2.

Your study records may be viewed for the purpose of source data audit by authorised persons within (eg Ethics Committee) or outside (eg sponsors or regulatory bodies) of the Hospital. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published.

11. Contacts

Study related questions can be directed to the Principal Investigator Dr Robyn O'Sullivan on 07 3397 1488 or Dr Tim Baird on 07 3394 7036.

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CONSENT FORM

Title	*Can mandibular advancement improve CPAP effectiveness in patients sub-optimally treated with CPAP using an oronasal mask?*
Short Title	*Combination therapy for OSA*
Protocol Number	*OVEN-006 V1.0 30th November 2016*
Project Sponsor	*Investigator*
Principal Investigator	*Dr Robyn O'Sullivan (PI)*
Co-Investigators	*Dr Tim Baird (CI)*
Location	*Greenslopes Private Hospital, Sleep Care Outpatient Sleep Clinic*

1. I, the undersigned ..... hereby consent to my involvement in the above study.
2. *Include here the details of the procedure proposed including the anticipated length of time it will take, the frequency with which the procedure will be performed, and an indication of any discomfort, which may be expected.*
3. I acknowledge that the nature, purpose and contemplated effects of the study so far as it affects me have been fully explained to me by the research worker and my consent is given voluntarily. I have also read and understand the Patient Information Sheet.
4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.
5. I have been given the opportunity to have a member of my family or a friend present while the study was explained to me.
6. I am informed that no information regarding my medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.
7. I understand that my involvement in the study will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the study at any stage without my future treatment being affected.
8.* "I understand that where biological material is collected, it may be stored and used for future research purposes either with my further consent or (in circumstances where my further consent cannot be obtained or is impractical to obtain) with the further specific approval of a hospital ethics committee set up in accordance with the NHMRC guidelines".
9.* I give permission for the release of information regarding progress in this study to the study centre, on the understanding that while the study centre will keep confidential results under my name, no published study will identify me in any way.
10.* I authorise the Greenslopes Private Hospital to allow access to relevant medical records to the investigators from .....
11. I have been told that this study has been approved by the Greenslopes Research and Ethics Committee.

Signed ..... **Date .....**

* If applicable (eg No.9 is usually applicable to clinical trials)
* No. 10 applies when investigators from other institutions are involved.