DEPT OF RESPIRATORY AND SLEEP MEDICINE
LEVEL 11, BUILDING 75
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

NSW GOVERNMENT Health
Sydney Local Health Network

Autoset CPAP versus Fixed CPAP in Obesity Hypoventilation Syndrome (APAP-OHS Project)

INFORMATION FOR PARTICIPANTS

Introduction

You are invited to take part in a research study looking at effectiveness of autotitrating continuous positive airway pressure therapy in people with obesity, sleep apnoea and chronically high carbon dioxide (CO_2) levels in the blood (APAP-OHS Project). The objective is to compare treatment responses of two different settings of continuous positive airway pressure (CPAP) devices in managing elevated CO_2 levels in the blood, sleep quality and circulatory health. The two settings are 'autotitrating' where the delivered pressure by the device changes depending on the perceived requirements based on the machine algorithm; and 'fixed' where the delivered pressure by the device is constant. Presently, it is unclear whether the autotitrating setting is equivalent to the fixed setting.

The study is being conducted within this institution by the following staff of the Department of Respiratory and Sleep Medicine:

- Dr Yizhong Zheng, MPhil Scholar
- A/Prof Craig Philips, Senior Scientist
- A/Prof Amanda Piper, Senior Physiotherapist
- A/Prof David Wang, Senior Scientist
- A/Prof Keith Wong, Staff Specialist
- A/Prof Brendon Yee, Staff Specialist
- Prof Ron Grunstein, Staff Specialist

Study Procedures

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be asked to undergo the following procedures:

- Random allocation of a particular mode of CPAP therapy
- Blood tests – this involves drawing of blood from your vein
- Electrocardiograph
- Pulse wave analysis – this involves recording of your blood flow waves from a blood pressure cuff; this should take less than 15 minutes to complete

- Questionnaires – there are three questionnaires to complete. Each one measures something different about your current level of functioning: general quality of life, how sleepy you feel and the overall quality of your sleep. These questionnaires will take about 20 minutes to complete.

After 3 months of using your allocated setting of positive pressure device (PAP machine) at home during sleep, you will again be reviewed in the sleep laboratory and all tests listed above will be repeated. In this way, we will be able to determine how you have responded to treatment.

Finally, the researchers would like to have access to your medical record to obtain information relevant to this study.

Risks

All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. In spite of all precautions, you might develop medical complications from participating in this study.

The risks of participating in this study are:

- Discomfort due to positive airway pressure therapy (nasal congestion, oral/nasal dryness, aeropagia)
- Discomfort from mask interface (claustrophobia, skin irritation, eye irritation)
- Inadequate control of sleep disordered breathing

Benefits

While we intend that this research study furthers medical knowledge and may improve treatment of obesity hypoventilation syndrome (OHS) in the future, it may not be of direct benefit to you.

We will however provide a loan positive airway pressure (PAP) machine for the 3 months of treatment with this device. It is to be returned after 3 months to the Sleep Department at Royal Prince Alfred Hospital.

Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate

medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

Costs

Participation in this study will not cost you anything, nor will you be paid.

Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

Confidentiality

All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

Further Information

When you have read this information, Dr Zheng will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact him on _____.

This information sheet is for you to keep.

DEPT OF RESPIRATORY AND SLEEP MEDICINE
LEVEL 11, BUILDING 75
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

Ethics Approval and Complaints

This study is being reviewed by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number _____.