

**A clinical trial of continuous positive airway pressure (CPAP) to improve lung function for patients who have abdominal surgery**

**PATIENT INFORMATION SHEET**

**Version 1.2 03/07/18**

**PI: [Insert PI name]**

**REC reference: 15/LO/1595**

### Introduction

We are inviting you to take part in a clinical trial, which we hope will improve the care of patients who have surgery. Before you decide, it is important to understand why we are doing this research and what it involves. Please take time to read the following information and decide whether or not you wish to take part. Talk to your friends and family about the trial if you wish. Ask us if anything is unclear.

### Why are we doing this research?

We are studying better ways to look after patients who have surgery. We hope these new techniques will help patients recover more quickly after surgery, so they can return home sooner, and in better health. One approach that may help is to use a device, which assists a patient’s breathing immediately after abdominal surgery. We think this may help patients recover better and so avoid complications such as chest infection, which can occur in a small number of patients. This trial will tell us which patients may benefit from the treatment.

### Why have I been invited?

We have invited you because your surgeon has recommended you for an operation where this treatment may have particular benefit.

### Do I have to take part?

No. It is up to you to decide whether or not to take part in the trial. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive.

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

Your operation will proceed as planned, and almost all of your treatment will not change. As you wake up after your surgery, you will either be offered extra oxygen through a loose facemask, which is the standard treatment, or you will be given a treatment to help you breathe more easily. This is called continuous positive airway pressure, or CPAP for short. It also involves extra oxygen but through a slightly tighter facemask, or a clear hood which looks a little like the helmet of a spacesuit. The choice of treatment is made at random, so neither you or your doctors will be able to choose which you receive. If you are offered CPAP, this will only be for the first four hours after you wake up from your operation. If you are allocated to receive the usual treatment of a loose facemask then none of your medical care will change. In the days after your surgery, we will come to see you and follow your recovery, reviewing your medical notes until you leave hospital. One month after your surgery and again one year after your surgery, we will contact you by telephone to see how you are doing and ask some brief questions about your general health. This telephone conversation will take less than five minutes. We may also contact your General Practitioner (GP) prior to contacting you, or if we are not able to reach you directly.

### What are the possible risks and benefits of taking part?

The risks of this trial to your health are very small. CPAP is very safe, and has been used in hospitals for many years. Some patients even use this at home to help them sleep. Occasionally people using CPAP can find the mask or hood uncomfortable, but small early studies suggest that CPAP should benefit most patients in this trial.

### What will happen if I don’t want to carry on with the trial?

You can stop the treatment at any time, but we would still like to follow your recovery because this will still provide important information about how well your treatment worked. If you prefer, you can request that you no longer take any part in the trial and we will not contact you or review your medical notes any further.

### What if I am not happy about the trial?

We will only make small changes to the way you are cared for in hospital. It is unlikely that these small changes would cause any problems. However, if you have a concern about any aspect of this trial, you should ask to speak with someone from the research team, who will do their best to answer your questions. You may also contact the doctors and nurses who lead the trial at this hospital on the telephone number at the bottom of this information sheet. You may also contact your Patient Advisory Liaison Service (PALS) [change according to site-specific department name] if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone [insert site specific telephone number] or email [insert site specific email]. You can also visit PALS [change according to site-specific department name as above] by asking at hospital reception. Queen Mary University of London has agreed that if you are harmed as a result of your participation in the trial, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the trial. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

### Confidentiality

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The information we collect about you will remain strictly confidential and nothing that might identify you will be revealed to any third party. Your medical notes will be seen by authorised members of the research team at your hospital so that they can collect information needed for this trial. Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998. Information from national databases will be obtained via strictly confidential communication. We are required by research regulations to keep the trial data for a minimum of 20 years after the trial has been completed. Occasionally, some patients lose touch with their hospital following their surgery and we will need to collect important basic information from national records. To ensure we identify you correctly, we will need to provide your name, date of birth, postcode and NHS number to the government agencies that keep these records. All data will be securely transferred and stored safely on NHS computers in line with strict regulations. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at http://www.jrmo.org.uk/

**Who is organising and funding the research?**

The trial is funded by the National Institute for Health Research, and the Association of Anaesthetists with support from a company that manufactures CPAP equipment. The trial is sponsored by Queen Mary University of London and run by the Critical Care and Perioperative Medicine Research Group at Queen Mary University of London. Your doctor will not receive any payment for including you in the trial.

### Who has reviewed the trial?

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect the interests of the patients who take part. This trial has been reviewed and granted a favourable opinion by the London - Central Research Ethics Committee and has also been approved by NHS Research and Development.

### Thank You

Thank you for considering taking part in this trial and for reading this information sheet, which is yours to keep. If you decide to take part in the trial, you will also be given a copy of your signed consent form.

Your trial doctor is:

Name: Contact phone number:

Your research/specialist nurse is:

Name: Contact phone number: