**High flow nasal oxygen for patients undergoing elective major abdominal surgery (PROTECT-HFNO) Trial**

**PARTICIPANT INFORMATION SHEET**

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Principal Investigator: [insert PI name]

IRAS: 350757

As part of the PROTECT programme, you are being invited to take part in the PROTECT-HFNO research study, intended to improve the care of patients having an operation involving their abdomen. Before you decide whether to take part, it is important to understand why this research is being done and what it involves. Please take time to read the following information. Talk to your friends and family about the study if you wish and 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. If we can show that patients and doctors are comfortable taking part in this small trial, we will then perform a much larger clinical trial that will tell us which patients may benefit from the treatment.

**Why have I been invited?**

You have been invited because you are going to have a surgery involving your abdomen.

**Do I have to take part?**

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you will be asked to sign a consent form. 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. If you decide not to take part, or later to withdraw, this will not affect any part of the care you receive.

**What would taking part involve?**

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 High Flow Nasal Oxygen, or HFNO for short. HFNO provides extra oxygen and is delivered through a nasal cannula device that sits just under your nose, as shown in the diagram below. The choice of treatment is made at random, so neither you or your doctors will be able to choose this. If you are offered HFNO, this will be for the first four hours after you wake up from your operation. If you are allocated to receive the usual treatment of standard facemask oxygen, then none of your medical care will change.

A drawing of a person with a breathing mask

Description automatically generated

**Diagram** showing a HFNO nasal cannula device

In the days after your surgery, we will come to see you and follow your recovery, reviewing your medical notes until you leave hospital at 30 days.

**What will happen if I don’t want to carry on with the study?**

If you decide not to take part, or later to withdraw, this will not affect any aspects of the care you receive. You are free to stop taking part at any time without giving a reason. if you decide to withdraw from the PROTECT-HFNO study, you will remain part of the PROTECT platform, unless you tell us otherwise. Please refer to the main PROTECT Platform Participant Information Sheet, under section ‘What will happen if I don’t want to carry on with the study?’.

**What are the possible benefits of taking part?**

Your breathing after surgery may be temporarily better if you take part in this study and are randomly chosen to receive HFNO, but we don’t know this for certain. By allowing us to collect information about HFNO used after your surgery and how you recover, we hope to work out if HFNO is helpful for patients recovering from surgery and this may help improve care of patients in the future.

**What are the possible disadvantages or risks of taking part?**

The treatment we are investigating is very safe and has been used in hospitals for many years. Regardless of which treatment you receive, you will be carefully monitored throughout the study to ensure any problems are detected and treated promptly.

**How will my information be used?**

You can find out how we will use your information by referring to the relevant sections in the PROTECT Participant information sheet that will be provided to you alongside this document.

**Who is funding the research?**

The study is funded by Barts Charity and the British Journal of Anaesthesia.

**What will happen to the results of this study?**

Once the study is complete, we will prepare and publish a scientific report. The results will be available to the hospitals that took part in the study. We may share information relating to the study in scientific meetings and it may be published in scientific journals. The results including a plain English summary of the findings will be published on the PROTECT website and you will be able to request a copy by contacting the study team via email: [admin@protectresearch.org](mailto:admin@protectresearch.org)

**Further Information**

Further information will also be available on the study website: <https://protectresearch.org>

**Thank you for taking time to read this information sheet.**

Your study doctor is:

Name: Contact phone number:

Your research/specialist nurse is:

Name: Contact phone number: