Hull and East Yorkshire Hospitals NHS Trust

cosy+

PATIENT INFORMATION SHEET

Comparison of orve+wrap with forced air warming blankets in managing patients' temperature following surgery

INTRODUCTION

You are being invited to take part in a research study called **COSY+,** which aims to determine the effectiveness of a new blanket in managing patients' temperature after surgery.

Before you decide whether to participate, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

This leaflet explains the purpose of this study in detail, about how the study will be carried out and what will happen to you if you take part. Please ask a member of the research team if there is anything that is not clear or if you would like further information. Ensure you take time enough to decide whether or not you wish to take part.

WHAT IS THE PURPOSE OF THIS STUDY?

We are looking at the **effectiveness** of a blanket called orve+wrap in the management of patients' temperature after surgery. This blanket is currently used by the Ambulance service.

We will compare how effective this blanket is compared to a technique called forced air warming (where warm air is blown into

an inflatable blanket and placed over you) in the theatre Recovery area.

WHY HAVE I BEEN INVITED?

You have been invited to take part because you are booked to have Surgery at Castle Hill Hospital. We hope to recruit 128 participants to this study.

DO I HAVE TO TAKE PART?

No. It is up to you to decide to join the study and your participation is completely voluntary. If you decide not to take part you will continue to receive the best standard of care available.

If you agree to take part and then change your mind and no longer wish to participate, you can withdraw your consent at any point without this affecting your future care.

Your legal rights will not be affected by giving consent to participate.

WHAT WILL HAPPEN IF I TAKE PART?

- Before your surgery; if you are happy to participate and have had any questions answered adequately, a member of the research team will ask you to sign a consent form for this research.
- Immediately before you have surgery, your temperature will be taken.
- You will have your surgery as normal.
- Following your surgery you will be transferred as normal from the operating room to the Recovery area.
- In the Theatre Recovery; your temperature will be taken every 10 minutes with two devices

- Firstly a probe will be placed in your ear; this is the usual method for measuring temperature in this hospital
- Secondly a small sticky sensor (the size of milk bottle lid) will be placed on your forehead. This will measure your temperature constantly and give a more accurate measure of your inner body temperature. (These two temperatures will be compared as part of the study).

If your temperature on arrival to the Recovery is between 35.0°C and 36°C (95°F to 96.8°F), you will be randomly allocated to receive one of the two blankets we are investigating.

WHAT IS RANDOMISATION

When we do not know which way of treating patients is best, we need to make comparisons.

To prevent the research team from biasing the results, the treatment you receive will be chosen by a process called **randomisation.** The treatment is randomly allocated by a computer; similar to making a choice by tossing a coin.

This means that you will have an equal chance of receiving **Forced Air Warming Blanket** or the orve+wrap **blanket.**

You and the team looking after you will know which treatment you are receiving.

WHAT ARE THE BLANKETS LIKE?

- The orve+wrap is a thin green sheet of material which has insulating qualities equivalent to an 11.5 Tog duvet. The ambulance service already uses these blankets to warm patients who are cold. These blankets will be pre-warmed in a blanket warmer before use.
- A Forced Air Warming Blanket is an inflatable blanket which is attached to a machine which constantly blows warm air

through it. A normal cotton sheet will be place over the top of this blanket. These blankets are currently the recommended method of warming patients who are cold after surgery.

Once you have received one of these blankets your temperature will be measured every 10 minutes, (which is normal procedure for patients immediately post-surgery) until you return to the ward.

WILL BEING IN THIS STUDY AFFECT MY CARE?

The care you will receive post operatively will have the same goals whether or not you take part in the study. The only difference is you will be randomised to either receive a forced air warming blanket or the Orve+wrap, to warm you up.

WHAT INFORMATION IS COLLECTED?

We will collect information on your theatre Recovery stay and ask your opinion with regards to comfort and temperature whilst you were in PACU. We will record details including your name, age and hospital number, which will allow us to see what antibiotics your had during you hospital stay.

WHO COLLECTS THIS INFORMATION?

Trained nurses in the Recovery area will record your temperature every 10 minutes.

Research nurses will collect the other relevant research data regarding your surgery and recovery.

All NHS professionals adhere to strict codes of confidentiality.

HOW IS THIS INFORMATION USED?

The information collected will be stored on a secured NHS computer system. Statisticians will analyse the information to determine if

Orve+ wrap is **as good** at managing patients' temperature post operatively as the forced air warming blankets.

All personal details will be removed from information leaving this NHS, so that nobody can identify you.

WHAT ARE THE BENEFITS OF TAKING PART?

We cannot promise that you will benefit from this study. Your participation will help us to identify the most effective way of managing patients' temperatures in the initial post-operative period and therefore improve the comfort and care in these patients.

WHAT ARE THE RISKS OF TAKING PART?

There are no perceived risks involved with taking part.

However, previous research investigating post-surgery hypothermia has shown a link between being cold and an increased risk of infections at the site of surgery. You will be closely monitored after surgery for signs of infection and appropriate treatment will be commenced if your surgical team believes it is required.

If on arrival to recovery your temperature is below 35°C you will not be randomised into the study and you will be re-warmed as per the usual hospital policy.

WHAT HAPPENS IF SOMETHING GOES WRONG?

You will be closely monitored in the theatre recovery area after your surgery and any side effects from being cold and then subsequently warmed will be treated as necessary by the clinical team looking after you.
If you are harmed by taking part in this research project, there are no special compensation arrangements.

If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it.
Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this research, the normal National Health Service complaints mechanisms are available to you.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

At the end of the study the information collected will be analysed and will be published in scientific journals and possibly presented at health related conferences. If you wish to see a copy of the final publication, please speak to a member of the research team. Individual patients will not be identified in any report or publications.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

Hull and East Yorkshire Hospitals NHS Trust have designed this study and are responsible for its management. A company called ORVEC International LTD who manufactures orve+wrap will provide the blankets and pay Hull and East Yorkshire Hospitals NHS Trust for research nurse time and for organising this study.

WHO HAS REVIEWED THIS STUDY?

All research undertaken in the NHS is looked at by an independent group of people called: The **Research Ethics Committee**. Their role is to protect your interests. This study has been reviewed by them and given a favourable opinion.

This study has also been reviewed by **Trans Humber Consumer Research Panel**; this is an independent patient and public involvement organisation who has offered suggestions to improve the study.

Two Independent Consultant Anaesthetists have reviewed the study and given their professional opinions in favour of the trial being conducted.

QUESTIONS ABOUT THE STUDY.

If you have any questions, concerns or would like to speak to the research team for any reason, please call a member of the team below on Tel: 01482 674457.

Research Nurses:

Mr Neil Smith

Mrs Caroline Abernethy

Mrs Victoria Martinson

Thank you for taking the time to read this information sheet and considering participation in this research.