

# A comparison of Orve+ Wrap and forced air warming blankets in managing patients' temperature following surgery

<b>Submission date</b> 28/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/01/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hypothermia (when body temperature drops below normal levels of 36°C) can be common after surgery and can effect patients' recovery, such as delaying wound healing and potential for increased surgical site infections plus an increased requirement for blood transfusion. Forced Air Warming (the process of blowing warm air through an inflatable blanket over the patient) is currently recommended by the National Institute Clinical Excellence (NICE) for patients experiencing hypothermia after surgery (post-operative). As Forced Air Warming requires dedicated equipment and the availability of electricity alternative methods which are just as effective in warming patients have been sought. The Orve+ Wrap is a new blanket available for warming patients but its clinical effectiveness has yet to be determined in the post-operative period. The aim of this study is to find out how effective the Orve+ Wrap warming blanket is compared to forced air warming blankets in patients who become hypothermic after surgery.

### Who can participate?

Adult patients who have planned orthopaedic surgery scheduled.

### What does the study involve?

After surgery when participants are admitted to the recovery area a temperature sensor is placed on their forehead to constantly measure of their temperature. If this temperature is less than 36°C, participants are given a blanket that either blows warm air over patients (Forced Air Warming) or a blanket that insulates patients Orve+ Wrap. The treatment that patients receive is chosen randomly by a computer programme with equal chance of getting each blanket. Participants then have their temperature monitored every 10 minutes until they leave the recovery area to assess the effectiveness of the blanket they used.

### What are the possible benefits and risks of participating?

It is unknown as to whether participants will benefit by taking part, however participants could help identify the most effective way of managing patients' temperatures in the initial post-operative period and therefore improve the comfort and care in future patients. 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. All participants will be closely monitored after surgery for signs of infection and appropriate treatment will be commenced if their surgical team believes it is required.

Where is the study run from?  
Castle Hill Hospital (UK)

When is the study starting and how long is it expected to run for?  
October 2014 to October 2017

Who is funding the study?  
Orvec International Ltd. (UK)

Who is the main contact?  
Mr Neil Smith  
neil.smith@hey.nhs.uk

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Neil Smith

**ORCID ID**  
<https://orcid.org/0000-0002-2598-9965>

**Contact details**  
Hull and East Yorkshire Hospitals NHS Trust  
HICU 1  
Hull Royal Infirmary  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ  
+44 1482 674457  
neil.smith@hey.nhs.uk

## Additional identifiers

**Protocol serial number**  
33006

## Study information

**Scientific Title**  
An open label, randomised controlled trial on the effectiveness of the Orve+ wrap blanket Vs forced air warming in restoring normothermia in the post anaesthetic Care Unit

**Acronym**

COSY+

**Study objectives**

The aim of this study is to look at how effective the Orve+ Wrap warming blanket is compared to forced air warming blankets in patients who become hypothermic ( $< 36^{\circ}\text{C}$ ) after surgery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Leeds West Research Ethics Committee, 25/08/2016, ref: 16/YH/0097

**Study design**

Randomised; Interventional; Design type: Treatment, Device

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Injuries and Accidents/ Complications of surgical and medical care, not elsewhere classified

**Interventions**

Participants are randomised to one of two groups electronically using sealed envelope™ (London, UK) on a 1:1 basis with stratification for Spinal and general anaesthesia and for age under 65 years or 65 years or greater.

Control arm: Patients will receive Forced Air Warming at the highest setting deemed clinical suitable.

Group 2: Patients will receive Orve+ Wrap for the duration of their Post Anaesthetic Care Unit stay or until the patient reaches normothermia ( $36.5^{\circ}\text{C}$ ) beforehand.

Patients in both groups will be followed up until hospital discharge

**Intervention Type**

Other

**Primary outcome(s)**

Mean temperature difference at 60 minutes post PACU admission using the zero heat flux thermometry Spot On (3m, Bracknell, UK)

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

30/11/2018

## Eligibility

### Key inclusion criteria

1. Patients aged >18
2. Planned elective or expedited orthopaedic surgery
3. Able to provide informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

129

### Key exclusion criteria

1. Lacks capacity to provide informed consent.
2. Current participation in an interventional research trial.
3. Unable to understand english both written and verbal.
4. Patients who are known to be pregnant.
5. Emergency/urgent surgery Known thyroid dysfunction

### Date of first enrolment

17/10/2016

### Date of final enrolment

20/11/2018

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Castle Hill Hospital**  
Castle Road  
Cottingham  
United Kingdom  
HU16 5JQ

## Sponsor information

### Organisation

Hull and East Yorkshire Hospitals NHS Trust

### ROR

<https://ror.org/01b11x021>

## Funder(s)

### Funder type

Industry

### Funder Name

Orvec International Ltd.

## Results and Publications

### Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2020	30/01/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V1.4	09/12/2016	09/12/2016	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes