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

**Submission date**
28/11/2016

**Recruitment status**
No longer recruiting

**Registration date**
09/12/2016

**Overall study status**
Completed

**Last Edited**
30/01/2020

**Condition category**
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 are 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 orthopeadic surgery scheduled.

What does the study involve?
After surgery when participants are admitted to the recovery area a temperature a 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
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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 (< 3 6°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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
See additional files

## 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°c) beforehand.

Patients in both groups will be followed up until hospital discharge

### Intervention Type
Other

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

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
10/10/2014

### Completion date
30/11/2018

## Eligibility

### Key inclusion criteria
1. Patients aged >18
2. Planned elective or expedited orthopeadic surgery
3. Able to provide informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 128; UK Sample Size: 128

### 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
England

United Kingdom

### Study participating centre
**Castle Hill Hospital**
Castle Road
Cottingham
United Kingdom
HU16 5JQ

## Sponsor information

### Organisation
Hull and East Yorkshire Hospitals NHS Trust

### Sponsor details
Hull Royal Infirmary
Anlaby Road
Hull
England
United Kingdom
HU3 2JZ

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/01b11x021

## Funder(s)

### Funder type
Industry

### Funder Name
Orvec International Ltd.

# Results and Publications

### Publication and dissemination plan
Plans are for publication in a peer reviewed journal with a focus on anaesthesia or perioperative management.

### Intention to publish date
31/03/2019

### 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? |
|---|---|---|---|---|---|
| Participant information sheet | version V1.4 | 09/12/2016 | 09/12/2016 | No | Yes |
| Results article | results | 01/04/2020 | 30/01/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |