

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	☐ Prospectively registered ☐ Protocol
Registration date 09/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/01/2020	Condition category Signs and Symptoms	☐ 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
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Contact information

Type(s)
Public

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