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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
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Contact information

Type(s)
Public

Contact name
Mr Neil Smith

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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