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Warming perioperative multilayer blanket assessment

Submission date
02/11/2017

Recruitment status
No longer recruiting

Registration date
05/12/2017

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypothermia (low body temperature) during and after operations, particularly those performed under general anaesthetic, used to be very common. Hypothermia has many side effects, including increased rates of wound infection, bleeding, cardiac (heart) events and thromboembolism (blood clots). Over the last 10 years there has been a revolution in the management of patient temperature during surgery. A variety of warming devices have been used, but principally forced warm air devices have been employed. These blow air over a heating coil, through a tube into a “blanket”, where the warmed air passes between two thin fabric layers which are next to the patient and then exit from the blanket. The blanket thus guides the warmed air around the patient. This has proved to be a reliable and effective method for maintaining patient temperature. Forced air warming has been shown to reduce infection rates in abdominal surgery when compared with surgery without a warming system, almost certainly due to the avoidance of patient hypothermia. However, a reduction in infection rates has not been proven in other types of surgery. Forced air warming (FAW) has been widely used in orthopaedics, including in patients undergoing hip and knee replacements. This is despite the effect of forced air warming on air flow around the patient. For nearly 50 years it has been appreciated that most wound infections after orthopaedic procedures are due to airborne contamination during the operation. As well as meticulous surgical technique and antibiotics, careful control of the airflow around the patient has been shown to reduce infection rates in arthroplasty surgery. The standard of care in the UK is for arthroplasty surgery to be performed in a laminar air unit, where surgeons wear a body exhaust suit and filtered air is passed vertically downwards around the patient by a fan unit mounted in the theatre ceiling. This system ensures that air passing around the open wound is filtered. This removes particles (principally skin scales shed by the theatre staff) from the air and reduces wound contamination. It has been reported that FAW may be associated with an increased rate of wound infection after arthroplasty. This is controversial. However, it is clear that FAW disrupts the airflow around patients undergoing operation in laminar air units. This is principally due to the development of convection currents due to the warm air exhausting from the blanket. It has been proposed that this increases the risk of wound contamination. A number of studies have confirmed the effect of FAW on air flow. Alternative methods for patient warming have been proposed. These include active devices (where additional heat is supplied to the patient) and passive devices (where the patient’s own body heat is retained by insulation). The only common alternative active method of warming to

FAW is the use of a heated mattress. These have been demonstrated to be effective, but are not disposable, and there is some evidence that shivering after surgery is more common with these devices than with FAW. In the current healthcare environment the need to clean the device between patients can pose a problem. There is a long history of the use of passive warming devices. A number of studies have been carried out of older single layer warming blankets (effectively reflective “space” blankets). These studies all demonstrate a significantly poorer performance at maintaining patient temperature compared with FAW. However, the single study of a modern multilayer blanket (Mediwrap) demonstrated equivalent performance to FAW. The aim of this study is to compare a multilayer passive blanket (Blizzard Blanket) against standard FAW in patients undergoing joint replacement surgery. The Blizzard blanket has been extensively used in prehospital care, particularly in the military environment. It appears to have superior thermal performance to the Mediwrap blanket. This device employs a combination of reflective and air based insulation. The device to be used in this study has been slightly modified from the prehospital Blizzard Blanket to reduce the noise from the blanket and to minimise allergy risks. It has slightly reduced thermal performance compared with the prehospital Blizzard device. Unlike FAW, this device will not affect the air flow in a laminar air unit which will minimise the risk of contamination of the wound at surgery. The device will be employed as a disposable.

Who can participate?
Patients undergoing primary total hip or knee replacement surgery

What does the study involve?
Participants are randomly allocated to be kept warm with either standard FAW or a Blizzard blanket. For the FAW group a Bair Hugger blanket is applied with standard practice (applied over the torso at the time of setting up the patient on the theatre operating table). The Bair Hugger is left in place until the patient leaves the operating theatre and is moved to recovery. Standard hospital blankets are then used to cover the patient when he/she is moved to the recovery bay. For the Blizzard blanket group the Blizzard blanket is applied with the patient in the standard operating position at the time of setting up the patient on the theatre operating table. The Blizzard blanket covers the torso and the non-operated leg. The Blizzard blanket is left in place until the patient leaves the recovery suite. Standard hospital blankets are then used to cover the patient when he/she is moved to the ward. Forehead temperature is measured using a thermometer at intervals during surgery (at the start and every 15 minutes), at the time of arrival into the recovery ward and at the time of return to the elective surgery ward.

What are the possible benefits and risks of participating?
It is thought that there are minimal risks involved. The known thermal performance of the Blizzard blanket is superior to the Mediwrap, which has already been shown to be equivalent to the Bair Hugger FAW for operations of a similar duration to arthroplasty surgery. The levels of wound contamination under present FAW systems are not clear, but this represents current standard UK practice. It is very difficult to see how the passive warming system could cause an increase in wound contamination.

Where is the study run from?
Ysbyty Gwynedd (UK)

When is the study starting and how long is it expected to run for?
March 2016 to May 2017

Who is funding the study?
1. Blizzard Protection Systems Ltd (UK)
2. Betsi Cadwaladr University Local Health Board (UK)

Who is the main contact?
Dr Simon Burnell
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.2

Study information

Scientific Title
Warming perioperative multilayer blanket assessment- a randomised controlled non-inferiority trial comparing a novel passive device with forced air warming to maintain normothermia in primary lower-limb arthroplasty surgery

Study objectives
Blizzard OR is not inferior to Forced Air Warming as a method of maintaining normothermia in primary lower-limb arthroplasty surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Betsi Cadwaladr University Health Board, 19/08/2016, ref: 16/WA/0188

Study design
Randomised controlled non-inferiority trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of intra-operative hypothermia

Interventions
This study compares a multilayer passive blanket (Blizzard Blanket, Blizzard Systems, Bethesda, Gwynedd) against standard FAW in patients undergoing joint replacement surgery. The Blizzard blanket has been extensively used in prehospital care, particularly in the military environment. It appears to have superior thermal performance to the Mediwrap blanket. This device employs a combination of reflective and air based insulation. The device to be used in the current trial has been slightly modified from the prehospital Blizzard Blanket, to reduce the noise from the blanket, to minimise allergy risks and to avoid any risks related to diathermy equipment. It has slightly reduced thermal performance compared with the prehospital Blizzard device. Unlike FAW, this device will not affect the air flow in a laminar air unit which will minimise the risk of contamination of the wound at surgery. The device will be employed as a disposable. Blizzard OR is made of 3 layers of polypropylene/polyethylene/aluminium with elastic threads of Elastane, Trevira CS and Grilon KE-85 covering yarns. The aluminium is of the form of flecks in a deposited ink layer which is non conductive.

Patients will be included after giving specific informed consent for the trial. They will be provided with a patient information document, and the proposed trial explained before surgery. They will be informed initially of the trial at the preoperative clinic and consent taken for the trial before admission for surgery. Randomisation is by sealed envelope arranged before trial and kept in the operating theatres.

FAW group: use of a Bair Hugger blanket applied with standard practice (applied over the torso at the time of setting up the patient on the theatre operating table). The Bair Hugger is left in place until the patient leaves the operating theatre and is moved to recovery; standard hospital blankets are then used to cover the patient when he/she is moved to the recovery bay.

Blizzard blanket group: the Blizzard blanket is applied with the patient in the standard operating position (lateral for total hip replacement; supine for total knee replacement) at the time of setting up the patient on the theatre operating table). The Blizzard blanket will cover the torso and the non operated leg. The Blizzard blanket is left in place until the patient leaves the recovery suite; standard hospital blankets are then used to cover the patient when he/she is moved to the ward.

All surgery will be carried out using standard techniques, including standard anti infection protocols (clean air theatre, occlusive gowns for surgeons, Stryker air hood, prophylactic antibiotics prior to incision).

Intervention Type
Device

Primary outcome(s)
Forehead temperature, measured using a temporal infra red thermometer at intervals during procedure (at start and every 15 minutes), at the time of arrival into the recovery ward and at the time of return to the elective surgery ward

Key secondary outcome(s))
Measured during stay in recovery ward on day of operation:
1. Postoperative pain, assessed by VAS as routinely administered at postoperative intervals
2. Recorded shivering
3. Blood loss, estimated by Hb drop across the operation
4. Days until mobile enough to go home

Completion date
31/05/2017

Eligibility

Key inclusion criteria
Patients undergoing primary total hip or knee replacement surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients unable to provide informed consent (learning difficulties, cognitive impairment)
2. Patients with a higher likelihood of developing infection (rheumatoid arthritis or other inflammatory arthropathy; patients on immunosuppressive drugs)
3. Patients with unusually complex primary arthroplasty (likely to last > 1h 45 minutes) (infection rates are partly determined by the length of time the wound is open, as is the likelihood of cooling)
4. Patients with a history or family history of hyper pyrexia related to anaesthesia

Date of first enrolment
01/11/2016

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Industry

Funder Name
Blizzard Protection Systems Ltd

Funder Name
Betsi Cadwaladr University Local Health Board

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data as spreadsheet of temperatures vs time & suitably anonymised will be available on request from Dr Simon Burnell (simon.burnell@wales.nhs.uk). These data could be used for any suitable analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes