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Are modern under-patient warming blankets as effective as forced-air warming blankets in preventing peri-operative hypothermia?

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
11/04/2016

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 occurs when body temperature drops below 35C (95F). Preventing hypothermia during surgery is beneficial for patients and there are many devices available to keep patients warm. The most commonly used warming device is the forced air warmer, which blows warm air through a special single-use blanket. However, this warming set up can interfere with the surgical field and has inherent cumulative costs. The aim of this study is to determine whether heating patients using a reusable resistive heated mattress is as effective as the more commonly used forced air warming blanket.

Who can participate?
Adult patients undergoing elective surgery

What does the study involve?
Participants are randomly allocated to be kept warm with either a forced air warming blanket or a resistive heating mattress when they were asleep. Both devices are already available and used routinely at our hospital. The participants' temperature is measured in the anaesthetic room, during the operation and at the end of surgery to allow us to assess which warming device was most effective.

What are the possible benefits and risks of participating?
The potential benefits include the ability to warm patients earlier in the resistive heating mattress group (since there was no requirement to apply a blanket and wait for surgical draping) and more intense temperature monitoring during the operation for both groups. The patients receiving resistive heating warming may also have had a reduced risk of developing pressure ulcers since there is some evidence suggesting favourable pressure-relieving properties of this mattress. It is however important to note that all patients who were deemed suitable for the study would have received warming and temperature monitoring regardless of whether they enrolled in the study or not. The risks of using any cutaneous warming device is that of burns. The forced air-warming may also affect theatre convection currents which can adversely influence the infection risk of patients receiving anaesthetics, particularly in laminar flow

theatres. With any electrical device there is also potential for exposure to electrical leakage currents.

Where is the study run from?
Brighton & Sussex University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2005 to February 2013

Who is funding the study?
Brighton and Sussex University Hospitals NHS Trust (UK)

Who is the main contact?
Dr C Mark Harper
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01056991

Secondary identifying numbers
N0051166184

Study information

Scientific Title

Are modern under-patient warming blankets as effective as forced-air warming blankets in preventing peri-operative hypothermia?

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised comparative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Peri-operative hypothermia

Interventions
This is intended to be a pilot randomised comparative study which will probably show equivalence and will allow power calculation for future randomised controlled trial which could prove a statistically significant difference if one exists.

Intervention Type
Device

Primary outcome measure
Post-operative core temperature being greater than or equal to 36 degrees Celcius.

Secondary outcome measures
Intra-operative blood loss

Overall study start date
18/08/2005

Completion date

01/02/2013

Eligibility

Key inclusion criteria
100 surgical patients being operated on in the supine position.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
18/08/2005

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hospital
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Brighton and Sussex University Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No