

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	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/04/2016	Condition category Signs and Symptoms	☐ 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

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT01056991

Protocol serial number

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

Primary study design

Interventional

Study design

Pilot randomised comparative study

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Intra-operative blood loss

Completion date

01/02/2013

Eligibility**Key inclusion criteria**

100 surgical patients being operated on in the supine position.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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

Funder(s)**Funder type**

Government

Funder Name

Brighton and Sussex University Hospitals NHS Trust (UK)

Results and Publications

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