

The effect of pre-operative warming on wound infection rates after clean surgery

Submission date 01/03/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0728

Study information

Scientific Title

Laser doppler flowmetry of skin circulation to measure the effects of using two warming therapies: a randomised clinical trial of surgical patients

Study objectives

To assess whether warming patients before short duration, clean surgery will reduce infection rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval information required at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Infection during surgery

Interventions

Patients were randomised to one of three groups:

1. Standard treatment - no warming
2. Local warming - a minimum of 30 minutes localised warming to the potential incision site using a warming dressing
3. Systemic warming - a minimum of 30 minutes warming to the whole body using a warm blown air blanket

Both warming devices were applied prior to surgery. A cohort of patients had laser doppler and TcPO₂ recordings taken prior to warming, after warming and after surgery.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Wound infection; masked outcome assessments made at 2 and 6 weeks

Secondary outcome measures

Added as of 07/01/2010:

1. Skin preparation; masked outcome assessments made at 2 and 6 weeks
2. Length of operation; masked outcome assessments made at 2 and 6 weeks
3. Administration of prophylactic antibiotics; masked outcome assessments made at 2 and 6 weeks
4. Experience of the operating surgeon; masked outcome assessments made at 2 and 6 weeks
5. Core temperature, measured before any treatment, after any warming, and after surgery

Overall study start date

01/01/2001

Completion date

31/12/2001

Eligibility

Key inclusion criteria

1. Patients having clean breast, varicose vein or hernia surgery

Added as of 07/01/2010:

2. Surgery results in a scar longer than 3 cm in length

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

421

Key exclusion criteria

Added as of 07/01/2010:

1. Under the age of 18 years
2. Pregnant
3. Taking long-term oral steroids
4. Received radiotherapy (to the incision site) or chemotherapy in the last 4 weeks
5. Had an infection at the time of surgery

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Professorial Unit of Surgery

Stockton-on-Tees

United Kingdom

TS19 8PE

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House

Horsham West Sussex

United Kingdom

RH12 2DP

Sponsor type

Charity

Website

<http://www.action.org.uk/>

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2001		Yes	No