ISRCTN54949546 https://doi.org/10.1186/ISRCTN54949546

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

Submission date 01/03/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/03/2001	**Overall study status** Completed	
Last Edited 07/01/2010	**Condition category** Surgery	

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 waming 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