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A comparison of patient warming versus prophylactic antibiotics on the reduction of wound infection after breast surgery

Submission date 02/12/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/02/2005	**Overall study status** Completed	
Last Edited 13/06/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.action.org.uk/research_projects/grant/232/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0978

Study information

Scientific Title
Patient warming versus prophylactic antibiotics on the reduction of wound infection after breast surgery: a randomised controlled trial

Study objectives
The principle objective is to compare the effect of local warming applied before and after surgery with prophylactic antibiotics on the rate of infection after breast surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee

Study design
Prospective randomised single-blinded 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
Breast surgery wound healing

Interventions
Group A: patients receive treatment with a standardised prophylactic antibiotic
Group B: patients receive treatment of warming to the chest area using an exothermic warming pad
Group C: patients receive both prophylactic antibiotic treatment and patient warming

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The rate of wound infection during the 30-day follow-up period.

Secondary outcome measures
1. Overall wound healing
2. Pain
3. Quality of life

Overall study start date
01/01/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Female patients greater than or equal to 18 years
2. Having clean, non-implant, breast surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
300

Key exclusion criteria
1. Under 18 years
2. Pregnant
3. Current infection
4. Fine wire biopsy
5. Implant surgery
6. Diabetic

Date of first enrolment
01/01/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tees and Hartlepool NHS Trust
Stockton-on-Tees
United Kingdom
TS19 8PE

Sponsor information

Organisation
North Tees and Hartlepool NHS Foundation Trust (UK)

Sponsor details
Research and Development Office
University Hospital of North Tees
Stockton-on-Tees
England
United Kingdom
TS19 8PE

Sponsor type
Hospital/treatment centre

Website
http://www.nth.nhs.uk/

ROR
https://ror.org/04zzrht05

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
Planned publication in a peer reviewed journal

Intention to publish date
31/12/2011

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	01/12/2011		Yes	No