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

| Submission date 02/12/2004          | <b>Recruitment status</b><br>No longer recruiting | <ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>        |
|-------------------------------------|---|---|
| <b>Registration date</b> 24/02/2005 | <b>Overall study status</b><br>Completed          | <ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul> |
| <b>Last Edited</b><br>13/06/2017    | <b>Condition category</b><br>Surgery              | Individual participant data   |

# 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

**Contact name** Prof David Leaper

## **Contact details**

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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

Female patients greater than or equal to 18 years
 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              |