

# The effects on post-operative pain of a warming dressing applied after hernia surgery

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/09/2014	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Andrew Melling

**Contact details**  
Clinical Research Nurse  
Professorial Unit of Surgery  
North Tees General Hospital  
Stockton-on-Tees  
United Kingdom  
TS19 8PE

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0159119156

## Study information

## **Scientific Title**

### **Study objectives**

The application of warmth to an area has traditionally been linked with reduction in pain. In this study this theory will be tested. Localised warming to the wound area will increase blood flow and therefore provide more oxygen to the wound. The increase in blood flow and post-operative tissue oxygenation in the wound area may help to reduce post-operative pain.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided 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**

Post-operative pain

### **Interventions**

Group A: Standard treatment (no warming)

Group B: Two hours of postoperative warming to the wound immediately after surgery and then the patients warm their wounds twice a day for the first three postoperative days at home. An exothermic warming pad that adheres to the wound dressing provides the warmth

Pain scores are recorded for the first four hours after surgery and then over the next two weeks by the patient. Wounds are observed independently and healing is assessed at weeks two and six.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

**Primary outcome measure**

1. Post-operative pain scores
2. Quality of life
3. Wound healing

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/2002

**Completion date**

31/12/2004

## Eligibility

**Key inclusion criteria**

Patients having hernia surgery (n = 180)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

180

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/09/2002

**Date of final enrolment**

31/12/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Clinical Research Nurse**  
Stockton-on-Tees  
United Kingdom  
TS19 8PE

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
North Tees and Hartlepool NHS Foundation Trust (UK)

## **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?
<a href="#">Results article</a>	results	01/03/2006		Yes	No