ISRCTN59897148 https://doi.org/10.1186/ISRCTN59897148

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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 30/09/2014	**Condition category** Surgery	

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?
Results article	results	01/03/2006		Yes	No