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Pressure sore risk in the operating department

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 25/09/2013	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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-
-
United Kingdom
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Additional identifiers

Protocol serial number
H23

Study information

Scientific Title

Study objectives
A comprehensive review of the literature reveals little information relating to the genesis of intra-operative pressure sores, and the contribution of operating room practice on aetiology is undefined. In an attempt to examine this area of clinical practice and answer the general question - is pressure sore prevention in the operating department possible? - a randomised trial of the 'standard' operating table mattress versus a dry polymer gel pad, involving patients who

are over 55 years scheduled for elective major vascular, general and gynaecological surgery is proposed.
Specific research questions include:
1. What are the benefits of using a dry polymer gel pad on the operating table in relation to intra-operative pressure sore incidence?
2. Which key variables are associated with intra-operative pressure sore development?
3. What is the extent of pre-operative pressure damage to skin?
Expected findings are speculative since little data is available. However, it is anticipated that a 75% lower incidence of intra-operative pressure sores will be observed in the treatment group (gel pad) when compared to the control ('standard') and that a preoperative prevalence of 10-30% is recorded. Potential benefits to the NHS include informed use of the dry polymer gel pad, cost savings associated with the prevention of pressure sores, and an improved ability to predict those at risk intraoperatively allowing more efficient targeting of preventative interventions. With regard to preoperative pressure sore development, the results will provide an indication of the scope of the problem.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery

Interventions
1. Use of dry polymer gel pad on the operating table
2. Standard treatment

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Pressure sore incidence

Key secondary outcome(s))
Not provided at time of registration

Completion date

30/04/1996

Eligibility

Key inclusion criteria
Patients who are over 55 years scheduled for elective major vascular, general and gynaecological surgery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/01/1994

Date of final enrolment
30/04/1996

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
United Kingdom
-

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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	01/08/1998		Yes	No