

Pressure sore risk in the operating department

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/09/2013	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Contact details
-
-
United Kingdom
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Pressure sore incidence

Secondary outcome measures

Not provided at time of registration

Overall study start date

08/01/1994

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

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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	01/08/1998		Yes	No