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Randomised controlled trial comparing alternating pressure overlays with alternating pressure mattresses for pressure sore prevention and treatment

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/08/2009	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 97/06/14

Study information

Scientific Title

Acronym
PRESSURE

Study objectives
The project will test the null hypothesis that there is no difference in clinical and cost-effectiveness between Alternating pressure Overlays (AO) and Alternating pressure mattress Replacements (AR).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval information added as of 20/07/2007: This study was approved by the North West Multicentre Research Ethics Committee and Local Ethics Committees.

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pressure sores

Interventions
Patients at moderate to high risk of developing a pressure sore will be randomised (stratified, 24 hour telephone) to either:

1. An Alternating-pressure Replacement mattress (AR)
2. An Alternating pressure mattress Overlay (AO)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The occurrence of a first or new sore at or above the level of superficial damage to the skin (break/blister) before discharge will be considered as a treatment failure.

Secondary outcome measures
1. Worsening/healing of existing sores
2. Patients' perceptions
3. Time to occurrence
4. Site of sore
5. Economic costs including those incurred in the treatment of pressure sores in the community, post-discharge

Skin assessments will be made daily by qualified attendant nursing staff and validated twice weekly by research nurses.

Health economic results comparing the costs and benefits of the expensive with the cheaper mattresses, will be expressed as incremental cost effectiveness ratios.

Overall study start date
01/05/2000

Completion date
31/10/2004

Eligibility

Key inclusion criteria
Patients aged > 55 years who are admitted to a vascular, orthopaedic or care of the elderly ward with an expected length of stay of at least 7 days AND who are completely immobile/have very limited mobility on admission; or have a pre-existing grade 1, 2 or 3 pressure sore on admission. Patients admitted before elective surgery who are expected to be completely immobile/have very limited mobility for at least 3 days after surgery may also be included.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1,972

Key exclusion criteria
Patients who have a pre-existing grade 4 or 5 pressure sore on admission, have participated in this trial previously or are unable/unwilling to give full informed consent.

Date of first enrolment
01/05/2000

Date of final enrolment
31/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Health Sciences
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Other publications	cost-effectiveness analysis	17/06/2006		Yes	No
Results article	results	17/06/2006		Yes	No
Other publications	HTA monograph:	01/07/2006		Yes	No