

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

Submission date

25/04/2003

Recruitment status

No longer recruiting

Registration date

25/04/2003

Overall study status

Completed

Last Edited

26/08/2009

Condition category

Skin and Connective Tissue Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

ROR
<https://ror.org/03sbpja79>

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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 | 17/06/2006 | | Yes | No |
| Other publications | cost-effectiveness analysis | 17/06/2006 | | Yes | No |
| | HTA monograph: | | | | |

[Other publications](#)

01/07/2006

Yes

No