

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

☐ Prospectively registered

☐ Protocol

Registration date

25/04/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/08/2009

Condition category

Skin and Connective Tissue Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Nicky Cullum

Contact details

Department of Health Sciences

University of York

Alcuin College

Area 2

Seebohm Rowntree Building

Heslington

York

United Kingdom

YO10 5DD

+44 (0)1904 321343

nac2@york.ac.uk

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

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

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