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Cost-effectiveness of the Australian medical sheepskin for the prevention of pressure ulcers in somatic nursing home clients

Submission date	Recruitment status	[X] Prospectively registered
08/02/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2011	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
N/A

Study information

Scientific Title

Study objectives
Research questions are:
1. What are the effects of appliance of Australian Medical Sheepskins on the incidence and prevalence rates of sacral pressure ulcers in somatic nursing home clients in the first month after admission compared to usual care?
2. What are the costs of appliance of Australian Medical Sheepskins compared to usual care?
3. What are the costs of the treatment for eventually developed pressure ulcers in the two study groups?
4. What adverse effects do Australian Medical Sheepskins have?
5. How do patients and nursing and caring personnel rate the (dis)comfort of Australian Medical Sheepskins and the ease of use of Australian Medical Sheepskins?

For this study we will consider the Australian Medical Sheepskin as effective if the incidence rate in the first month after admission is at least (absolute) 10% less in the experimental group than in the control group and the prevalence numbers at two moments during the research period are (absolute) 10% lower in the
experimental group than in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (METC Universitair Medisch Centrum Utrecht) on the 2nd January 2007 (ref: NL14075.041.06).

Study design
Randomised, active-controlled, parallel group multicentre 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
Pressure ulcers

Interventions
Australian Medical Sheepskin plus usual care during first 30 days after admission to a nursing home versus usual care only.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Incidence and prevalence of pressure ulcers on the sacrum in the first month after admission
2. Costs

Secondary outcome measures
1. Sacrum pressure ulcer free days
2. Adverse events
3. Comfort/ease of use

Overall study start date
01/05/2007

Completion date
01/11/2008

Eligibility

Key inclusion criteria
1. Adults
2. Admitted for a somatic reason
3. Free of sacral pressure ulcer
4. Not having a darkly pigmented skin (because of difficulty to diagnose stage one ulcer)
5. Having an expected stay of more than one week

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
750

Key exclusion criteria
1. Admitted for a primarily pyscho-geriatric reason
2. Having sacral pressure ulcers at admission

Date of first enrolment
01/05/2007

Date of final enrolment
01/11/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Netherlands Institute for Health Services Research (NIVEL)
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Sponsor information

Organisation
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Sponsor type
Research organisation

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ROR
https://ror.org/015xq7480

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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?
Protocol article	protocol	07/01/2008		Yes	No
Results article	results	01/11/2011		Yes	No