

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

Submission date 08/02/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/07/2011	Condition category Skin and Connective Tissue Diseases	<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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Admitted for a primarily psycho-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)
Utrecht
Netherlands
3500 BN

Sponsor information

Organisation

Netherlands Institute for Health Services Research (NIVEL) (The Netherlands)

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

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	01/11/2011		Yes	No
Protocol article	protocol	07/01/2008		Yes	No